THE EFFICACY OF SUNFLOWER OIL IN THE PREVENTION OF STRIAE GRAVIDARUM

NICHA JENMANACHAIYAKUN

MASTER OF SCIENCE
IN
DERMATOLOGY

SCHOOL OF ANTI-AGING AND REGENERATIVE MEDICINE
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ABSTRACT

Background: Striae gravidarum occur in 50% to 90% of women. The exact cause is still unclear. No definitive method has been shown to be effective in preventing the development of striae gravidarum. They can be a source of anxiety and lack of self-confidence resulting in a compromised quality of life.

Objective: To study the efficacy of sunflower oil in the prevention of striae gravidarum

Methods: Thirty-two nulliparous women between the ages of 18 and 40 years with gestational ages between 16 and 18 weeks were selected for the study and randomly placed into two groups. Each participant was instructed to apply the sunflower oil and the placebo randomly on each side of the abdomen twice daily until the time of delivery. The width of striae, photographs, pruritus score and side effects were evaluated every two weeks until delivery. Participant satisfaction was evaluated at week 10 and at delivery.

Results: Overall, the incidence of striae gravidarum was 55.4%. The incidence of striae gravidarum was 53.6% in the sunflower oil group and 57.1% in the placebo group. No statistical significance in the prevention of striae gravidarum was evident (p = 0.711). The mean gestational age at which striae gravidarum first appeared was

31.46 ± 5.02 weeks. The incidence of no significant striae in the sunflower oil group was 25.0%, while in the placebo group was 12.5%. The incidence of mild striae in sunflower oil group and placebo group was 25.0% and 31.3% respectively. The incidence of moderate striae in both groups was equal being 31.3%. The incidence of severe striae in sunflower oil group and placebo group was 18.8% and 25.0% respectively. The mean width of striae at delivery in sunflower oil group and placebo group was 2.90 ± 1.40 mm and 3.44 ± 1.15 mm respectively. There was no statistically significant difference in the mean width at delivery between both groups (p = 0.137). For the global photographic score, participant satisfaction and mean pruritus score, the results demonstrated no statistically significant difference between sunflower oil group and placebo group. There were few side effects.

Conclusion: In terms of incidence and severity, the results demonstrated no benefits of the use of sunflower oil. There was no significance in the prevention of striae gravidarum.

Keywords: Striae gravidarum/Sunflower oil/Prevention

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CHAPTER 1

INTRODUCTION

1.1 Background

Striae are a very common skin condition that can be found in all age groups. Striae are characterized by linear depressions in the skin that develop in areas of dermal damage resulting from stretching of the skin (Bolognia, Jorizzo, & Rapini, 2007). Additionally, there are many factors associated with striae which include puberty, pregnancy, growth spurts, rapid weight gain or loss, obesity (Garcia-Hidalgo et al., 1999), and disorders that lead to hypercortisolism (Bolognia et al., 2007).

Striae were first reported by Roederer in pregnant women in 1773. Later in 1889, Troisier and Menetrier presented the first histologic descriptions (Bolognia et al., 2007).

Striae usually develop between the ages of 5 and 50 years. They occur mostly during puberty or pregnancy, with an incidence of 25%-35% (Ammar, Rao, Schwartz, & Janniger, 2000) and 75% respectively (Muzaffar, Hussain, & Haroon, 1998). Striae are more common in Caucasians. They occur about twice more frequently in women as compared to men (Bolognia et al., 2007).

The factors that lead to the development of striae are poorly understood. Striae distensae are the results of breaks in the connective tissue that lead to dermal atrophy. Other factors that may influence the development of striae include hormones (especially corticosteroids), mechanical stress and genetic predisposition (Goldsmith et al., 2012).

Striae usually present as multiple, symmetric, well-defined linear atrophic lesions that follow the lines of cleavage. During early stage (striae rubra), the lesions are red-to-violaceous that may be raised and irritable. Over time, the color gradually fades, and in the late stage (striae alba), the lesions become atrophic with the skin surface showing a fine, white, wrinkled appearance. Striae are irregularly linear, several centimeters long

and 1-10 millimeters wide. Striae alba are usually permanent, but after some years they may fade (Burns, Breathnach, Cox, & Griffiths, 2010).

In puberty, striae may develop soon after the appearance of pubic hair. They occur in areas where there is a rapid increase in size. The most common locations of striae in girls are the thighs, hips, buttocks and breasts. The most common locations of striae in boys are the shoulders, outer aspect of thighs and lumbosacral region. Adolescent striae can also be seen on abdomen, upper arms, neck and axillae, but their occurrence is rare (Bolognia et al., 2007).

In pregnancy, the most common location of striae is the abdomen; the breasts and thighs are less commonly involved. Initially they appear on the abdominal wall, but later they may involve the breasts. Striae usually develop during the last trimester. They are more common in younger primigravidas than in older pregnant women (Bolognia et al., 2007).

Striae can also be induced by both local and systemic steroid therapy. Striae secondary to topical steroid use usually affect the flexural and intertriginous areas. They may disappear or become less visible when the treatment is stopped. Striae induced by systemic steroid therapy and Cushing's syndrome are usually larger, more widely distributed and involve other regions, sometimes even including the face (Burns et al., 2010).

The histologic findings vary depending upon the stage of striae at the time of biopsy. In early stages, inflammatory changes may be present. The dermis is edematous. There is perivascular infiltration of lymphocytes. In later stages, the epidermis becomes thin, flattened and atrophic with blunted rete ridges. There is a decrease in the thickness of the dermis. The upper portion of the dermis shows straight, thin collagen bundles arranged parallel to the skin surface and transverse to the direction of the striae. The elastic fibers are also arranged similarly. In early lesions, there are more of fine elastic fibers, but in older lesions these are replaced by thick elastic fibers (Lever, Elder, Elenitsas, Johnson, & Murphy, 2009). Dermal elastin can be fragmented. Elastic staining shows a decrease in elastin content as compared to the adjacent normal dermis (Arem & Kischer, 1980). Both sweat glands and hair follicles are absent within striae (Goldsmith et al., 2012).

Striae distensae do not cause any significant medical problems because they rarely become ulcerated. However, they are more of a cosmetic concern for many women. They can be a source of anxiety, stress and lack of self-confidence, which can compromise their quality of life (Yamaguchi, Suganuma, & Ohashi, 2012). Since the exact cause of striae distensae is still unclear, no definitive method has been shown to be effective in preventing and treating the striae distensae. There are two main types of treatment which involve chemical and physical methods. Chemical methods involve the use of topical application of creams, chemical peeling and herbal therapy. Physical methods involve the application of lasers, intense pulsed light, radiofrequency, needling therapy and microdermabrasion (Elsaie, Baumann, & Elsaaiee, 2009).

For topical therapy, several studies have shown that 0.1% tretinoin cream is effective in the treatment of early stage lesions (striae rubra). It can improve their appearance and decrease the length and width of striae (Kang, 1998). The disadvantage of this treatment is its contraindication in pregnant women because topical derivatives of vitamin A may affect the fetus.

For chemical peeling 0.05% tretinoin/20% glycolic acid and 10% L-ascorbic acid/20% glycolic acid, may improve the appearance of striae (Ash, Lord, Zukowski, & McDaniel, 1998). The side effects of chemical peeling are skin redness, rash, pruritus, scaling and increased skin sensitization.

Physical methods as shown in many studies are effective in the treatment of striae.

Examples of laser therapy:

1. 585 nm Pulsed dye laser
2. 585 nm Pulsed dye laser in combination with radiofrequency
3. 308 nm Excimer laser
4. 577-511 nm Copper bromide laser
5. 1064 nm Nd:YAG laser
6. 1550 nm Erbium-glass fractional laser
7. 10,600 nm Carbon dioxide fractional laser

Since the etiology of striae is unknown, there is still no definitive method available for the prevention and treatment of striae. In general, the effective treatment of striae rubra may be topical derivatives of vitamin A. However, the drug cannot be used in pregnant women. The use of vitamin A derivatives for the prevention of striae

gravidarum may be associated with teratogenicity. Therefore herbal therapy is an alternative topical treatment modality for pregnant women. The advantages of herbal therapy include fewer complications, less cost and increased compatibility for pregnant women as compared to chemical peeling and laser therapy. A number of oils like olive oil, almond oil and cocoa butter can possibly be used for the prevention of this condition. According to a previous study conducted on olive oil which is a rich source of vitamin E, has been shown to reduce the incidence of severe striae gravidarum (Soltanipoor, Delaram, Taavoni, & Haghani, 2012). Therefore our study is conducted on the sunflower oil which has more content of vitamin E than the olive oil. The purpose is to study the efficacy of sunflower oil in the prevention of striae gravidarum.

1.2 Research Question

Does the sunflower oil reduce the incidence and severity of striae gravidarum?

1.3 Objectives

1.3.1 General objective

To study the efficacy of sunflower oil in the prevention of striae gravidarum

1.3.2 Specific objectives

1.3.2.1 Primary outcomes

1. To compare the incidence of striae gravidarum between sunflower oil and placebo

2. To compare the severity of striae gravidarum between sunflower oil and placebo

1.3.2.2 Secondary outcomes

1. To compare the width of striae gravidarum between sunflower oil and placebo

2. To compare the global photographic score between sunflower oil and placebo

3. To compare the participant satisfaction between sunflower oil and placebo

4. To compare the pruritus score between sunflower oil and placebo

5. To evaluate the side effects that occur between sunflower oil and placebo

1.4 Hypothesis

The sunflower oil has a higher efficacy in preventing striae gravidarum than the placebo.

1.5 The Scope of Research

Participants included 25 nulliparous women between the ages of 18 and 40 years with gestational ages between 16 and 18 weeks, who attended Pranangklao hospital for prenatal care. Participants were willing to participate in the research in order to prevent striae gravidarum. Each participant was instructed to apply the sunflower oil and the placebo randomly on each side of the abdomen twice daily until the time of delivery. The width of striae, photographs, pruritus score and side effects were evaluated every two weeks until delivery. Participant satisfaction was evaluated at week 10 and at delivery. The duration of the research was five months from September 2013 to January 2014.

1.6 Conceptual Framework

There are many methods aimed at preventing and treating striae gravidarum. Herbal therapy is one of the methods of complementary and alternative medicine. Various oils have been used including olive oil and almond oil. The sunflower oil can be used to prevent striae gravidarum due to the fact that it is rich in vitamin E. Vitamin E is the main modulator for collagen synthesis which acts by activating fibroblasts (Makpol, Azura Jam, Anum Mohd Yusof, & Zurinah Wan Ngah, 2011). Therefore the principle of

using sunflower oil to prevent striae gravidarum is based on the idea of increasing collagen synthesis. Although there are other conditions that can cause striae as well, they are however excluded from this study.

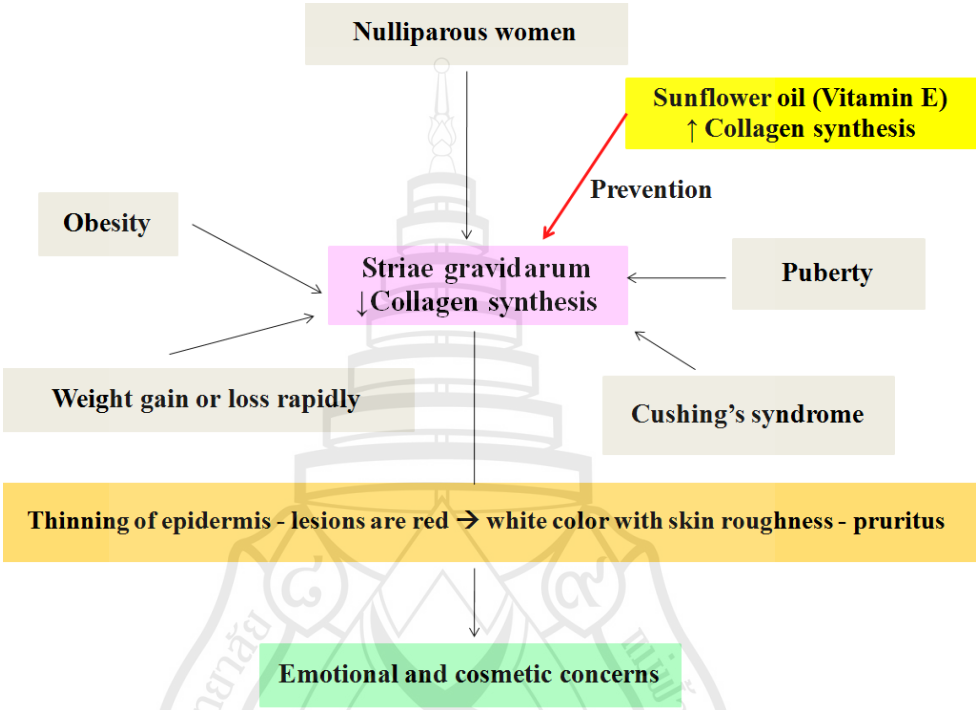


Figure 1.1 Conceptual Framework

1.7 Operational Definitions

1.7.1 Striae distensae

Linear depressions in the skin that develop in areas of dermal damage resulting from stretching of the skin. There are two stages; striae rubra and striae alba.

1.7.2 Striae gravidarum

Striae distensae that occur due to physiologic changes during pregnancy.

1.7.3 Striae rubra

Striae in the early stage can be seen as reddish or purplish lines that develop perpendicular to the direction of skin tension.

1.7.4 Striae alba

Striae in the late stage can be seen as whitish because the color fades over time. The skin surface becomes atrophic.

1.7.5 Sunflower oil

The oil is compressed from sunflower (*Helianthus annuus*) seeds. It is a combination of monounsaturated and polyunsaturated fats with low saturated fat levels. It has high vitamin E content.

1.7.6 Vitamin E

A group of eight fat-soluble compounds that include both tocopherols and tocotrienols. There are many different forms of vitamin E. γ-tocopherol is the most common form. α-tocopherol is the most biologically active form of vitamin E.

1.7.7 Digital vernier

A precision instrument that can be used to measure the length and width of striae.

1.7.8 The Fitzpatrick Skin Phototype Classification

Table 1.1 The Fitzpatrick Skin Phototype Classification

Skin phototype	Typical features	Tanning ability
I	Redhead, freckled, Celtic, Irish-Scots	Always burns easily, never tans (sensitive)
II	Fair-skinned, fair-haired, blue-eyed Caucasians	Always burns easily, tans minimally (sensitive)
III	Darker Caucasians	Burns moderately, tans gradually (to a light-brown) (normal)

Table 1.1 (continued)

Skin phototype	Typical features	Tanning ability
IV	Mediterranean type Caucasians	Burns minimally, always tans well (to a moderate brown) (normal)
V	Mid-Eastern, some Latin American types	Rarely burns, tans profusely (to a dark-brown) (insensitive)
VI	Black skinned Negroids	Never burns, deeply pigmented (insensitive)

Source Cripps (1981)

1.7.9 The severity of striae gravidarum

No striae	=	0	No erythema	=	0
< 5 Striae	=	1	Mild erythema (light pink or red)	=	1
5-10 Striae	=	2	Marked erythema (dark red)	=	2
> 10 Striae	=	3	Violaceous erythema (purple)	=	3

The abdomen is divided into four quadrants. In each quadrant, striae are scored up to a maximum of 6; a score of 0 to 3 for the number of striae and a score of 0 to 3 for the degree of erythema. The maximum total score for each side of the abdomen is 12.

A total score of 1 to 3 represents “no significant striae”.

A total score of 4 to 6 represents “mild striae”.

A total score of 7 to 9 represents “moderate striae”.

A total score of 10 to 12 represents “severe striae”.

Modified from (Atwal, Manku, Griffiths, & Polson, 2006)

1.7.10 The global photographic score

-3	=	Greatly decreased	0	=	No change
-2	=	Moderately decreased	1	=	Slightly increased
-1	=	Slightly decreased	2	=	Moderately increased
			3	=	Greatly increased

The photographs are evaluated before intervention and after intervention by three physicians.

1.7.11 Participant satisfaction

The satisfaction is presented in visual analog scale ranging from 0% to 100%.

0%-20%	=	Slight improvement
20%-40%	=	Mild improvement
40%-60%	=	Moderate improvement
60%-80%	=	Good improvement
80%-100%	=	Very good improvement

1.7.12 The pruritus score

The pruritus score is presented in visual analog scale ranging from 0 (no pruritus) to 10 (severe pruritus).

1.8 Limitations

1.8.1 Population and sample size limitations

1.8.2 Since time is limited, so a long term follow-up cannot be achieved.

1.8.3 Restrictions of pregnant women to use any type of drugs

1.9 Expected Benefits and Applications

1.9.1 Herbal therapy is an alternative medicine for the prevention of striae gravidarum. The benefits are few complications, low cost and increased compatibility for pregnant women.

1.9.2 Serve as a database for further study in the future

CHAPTER 2

LITERATURE REVIEW

2.1 Striae Distensae

2.1.1 Epidemiology

Striae are a very common skin condition found in nearly all age groups. They usually develop between the ages of 5 and 50 years. Overall, the incidence of striae development during puberty is 25%-35%, while the incidence of striae development during pregnancy is approximately 75% (Bolognia et al., 2007). Rates of occurrence of striae gravidarum vary ranging between 50% and 90% (Osman, Rubeiz, Tamim, & Nassar, 2007). The incidences in primiparous women are reported to be 52% (Atwal et al., 2006), 61% (Osman, et al., 2007) and 87.7% (Ghasemi, Gorouhi, Rashighi-Firoozabadi, Jafarian, & Firooz, 2007) in different studies. In Thailand, the prevalence of striae gravidarum is 77% (J-Orh, Titapant, Chuenwattana, & Tontisirin, 2008).

Striae occur about twice as frequently in women as in men. They are more common in Caucasians (Bolognia et al., 2007), but one study found that non-white women are also at greater risk (Chang, Agredano, & Kimball, 2004). Striae gravidarum are common during the first pregnancy (Salter & Kimball, 2006). They usually present during the third trimester (Atwal et al., 2006; Cunningham et al., 2009). It is observed that the mean gestational age at which striae gravidarum first appear is 27.57 ± 5.38 weeks (Ghasemi et al., 2007). However, Chang reported that striae gravidarum are present in women under 24 weeks of gestational age, and there are also cases where women developed their first striae during a second pregnancy (Chang et al., 2004).

2.1.2 History

Striae were first described by Roederer in 1773. They are “visible linear scars” (Rook & Burns, 2004) that have evolved through stages (Kang et al., 1996). The stages are similar to the stages of tissue healing or scar formation (Elson, 1990; Kang, 1998; Salter & Kimball, 2006). There are two stages.

2.1.2.1 An early stage is an inflammatory phase known as striae rubra (Gilmore, Vaughan, Madzvamuse, & Maini, 2012). They are characterized as reddish slightly depressed streaks (Cunningham et al., 2009) or reddish purple linear patches (Reece & Hobbins, editors, 2007).

2.1.2.2 A late stage is a chronic phase known as striae alba (Gilmore et al., 2012). They fade gradually (Gabbe et al., 2007; Kang, 1998; Kang et al., 1996; Salter & Kimball, 2006) leaving glistening (Cunningham et al., 2009), white depressed (Elson, 1990) or pale wrinkled lines (Watson et al., 1998) on the skin.

Striae develop most commonly during adolescence and pregnancy. However, they may occur in other conditions such as Cushing’s syndrome, Marfan’s syndrome, prolonged use of topical steroids; where pathology in the dermis is existent. Striae may also occur in association with changes to body habitus for example weight loss, cachexia, obesity or body-building (Gilmore et al., 2012).

The risk factors that have been associated with the development of striae gravidarum include family history of striae gravidarum in mother, diabetes in pregnancy (Cunningham & Williams, 2005), race, skin type, younger maternal age (Gabbe et al., 2007), baseline and delivery body mass index, weight gain more than 11.5-15.5 kilograms within pregnancy period (Osman et al., 2008) and extreme abdominal and hip girths. The weight, height and head circumference of the newborn can also contribute to their development (Ghasemi et al., 2007).

2.1.3 Etiology

The exact causes of striae remain unknown; however several theories have been proposed.

2.1.3.1 The stretch theory

The “stretch theory” was proposed by early researchers around the year 1861. This theory was proposed by Wilks and was widely accepted as the cause of

striae gravidarum. There has been some debate about the etiology of skin stretching in striae: one group could not find any relationship between striae and the increase in abdominal girth among pregnant women (Poidevin, 1959). It has been argued that striae are rarely found over the extensor surfaces of joints; the area of skin over a joint that is stretched when the joint is flexed, and the skin is subject to physiologic stretching (Nigam, 1989).

2.1.3.2 The hormone theory

In 1959, other factors that contributed to the development of striae were highlighted, and among them increasing adrenal cortical activity is considered a prominent etiology. From the study of Poidevin in 116 primigravida women, he concluded that the development of striae gravidarum is not only due to stretching. He found the relationship between striae and impaired glucose tolerance in pregnancy which is a sign of adrenocortical hyperactivity. Other researchers also found the link between increased adrenocortical hormonal activity and striae gravidarum (Liu, 1974; McKenzie, 1971). There are other hormones associated with the development of striae. Oestrogen and relaxin are thought to promote the formation of a type of mucopolysaccharide ground substance which contributes to the separation of the collagen fibrils (Bryant, Greenwell, & Weeks, 1968) and the formation of striae gravidarum in response to stretch (Liu, 1974).

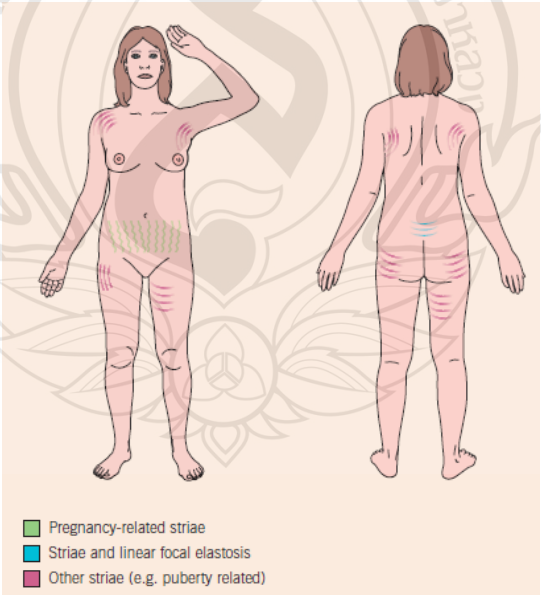
2.1.3.3 The connective tissue related stretching theory

In 1979, Shuster argued that the hormones of pregnancy may alter the collagen fibrils, but there is no evidence to support this notion. He suggested that striae are always due to stretching but only occur in immature connective tissue characterized by a "critical titre of rigid cross-linked collagen and elastic unlinked collagen" (Shuster, 1979). In 2004, Archer found the disrupted collagen mechanism which involves irreversible sliding and separation of fibers in pregnant women (Archer, 2004). In 1998, Watson suggested that the development of striae is related to changes in the dermal elastic fibers rather than the collagen. They thought that striae may occur in cases where there is a deficiency of cutaneous fibrillin. The extra strain or stretching in pregnancy is enough to tear the elastic fiber network, resulting in the formation of striae (Watson et al., 1998).

There is no conclusive evidence to support the idea that striae are scars. They are not due to rupture of the connective tissue in response to stress. However, the arrangement of elastic fibers and collagen is similar to a scar. Striae are characterized by absent rete ridges with a thinning and flattening of the overlying epidermis (Zheng, Lavker, & Kligman, 1985). Sweat glands or hair follicles do not exist within the striae.

2.1.4 Clinical features

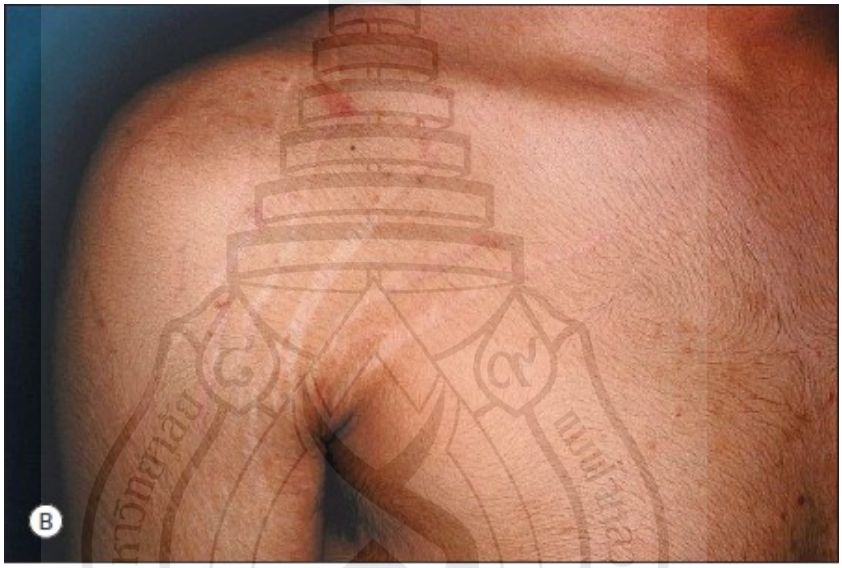
Striae are irregular, well-defined linear atrophic lesions. They usually present as multiple and symmetrically distributed lesions along the lines of cleavage. There are two stages of their evolution which are striae rubra and striae alba. In early stage (striae rubra), the lesions are red-to-violaceous that may be raised and irritable. In the later stage (striae alba), the lesions become atrophic with the skin surface showing a fine, white, wrinkled appearance as the color fades over time. Striae alba are usually permanent, but after some years they may fade. They rarely become ulcerated. Striae are several centimeters in length and 1-10 millimeters in width (Burns et al., 2010).



Source Bolognia et al. (2007)

Figure 2.1 Common Anatomic Distribution of Striae

Striae are common during puberty and pregnancy. In puberty, striae may develop soon after the appearance of pubic hair. They occur in areas where there is a rapid increase in size. The most common sites of striae in girls are the thighs, hips, buttocks and breasts. The most common sites of striae in boys are the shoulders, outer aspect of thighs and lumbosacral region. Among weightlifters, anterior shoulders, thighs and lower back are the preferred sites of striae. Other less common sites of adolescent striae include abdomen, upper arms, neck and axillae (Bolognia et al., 2007).

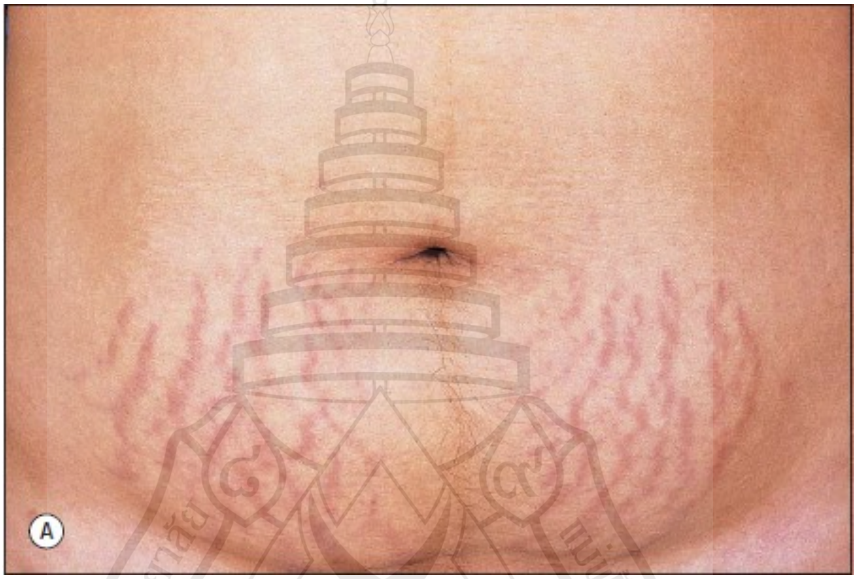


Source Bolognia et al. (2007)

Figure 2.2 Atrophic Linear Lesions of Striae Alba in a Teenager

In addition, striae can also be induced by both local and systemic steroid therapy. Striae secondary to topical steroid use usually affect the flexural and intertriginous areas. They are likely to occur with potent topical steroid use, especially under occlusion. However, striae may disappear or become less visible when the treatment is stopped. Striae induced by systemic steroid therapy and Cushing's syndrome are usually larger, more widely distributed and involve other regions, sometimes including the face (Burns et al., 2010).

In pregnancy, the most common location of striae is the abdomen, whereas the breasts and thighs are less commonly involved. Initially they appear on the abdominal wall, but later they may involve the breasts. Striae usually develop during the last trimester. They are more common in younger primigravidas than in older pregnant women (Bolognia et al., 2007).



Source Bolognia et al. (2007)

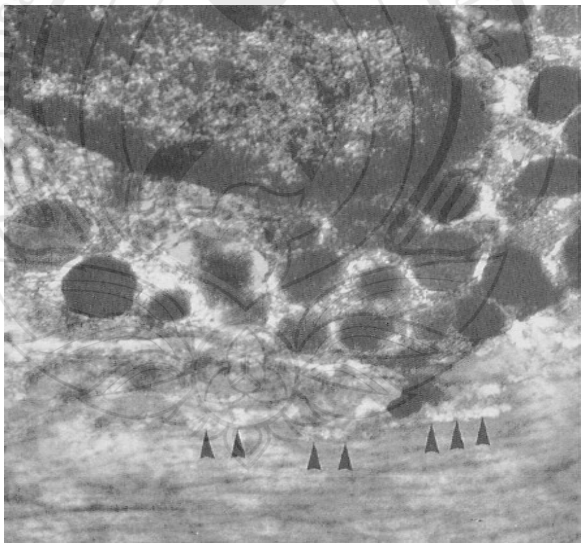
Figure 2.3 Linear Erythematous Lesions on the Abdomen (Striae Rubra)

Atwal developed a numerical system to measure the severity of striae gravidarum focusing on the number of striae and the degree of erythema. The sites of examination include the four common areas of striae which are abdomen, hips, breasts and thighs/buttocks. At each site, striae are scored up to a maximum of 6; a score of 0 to 3 for the number of striae and a score of 0 to 3 for the degree of erythema. The number of striae is recorded as follows; no striae = 0, < 5 striae = 1, 5-10 striae = 2, > 10 striae = 3. The degree of erythema is recorded as follows; no erythema = 0, mild erythema (light pink or red) = 1, marked erythema (dark red) = 2, violaceous erythema (purple) = 3. The maximum total score is 24. A total score of 0 to 3 represents “no significant striae”. A total score of 4 to 9 represents “mild

striae". A total score of 10 to 15 represents "moderate striae". A total score greater than 16 represents "severe striae" (Atwal et al., 2006). Other criteria for assessing the severity of striae gravidarum consist of scaling, burning or pruritus (Kang et al., 1996).

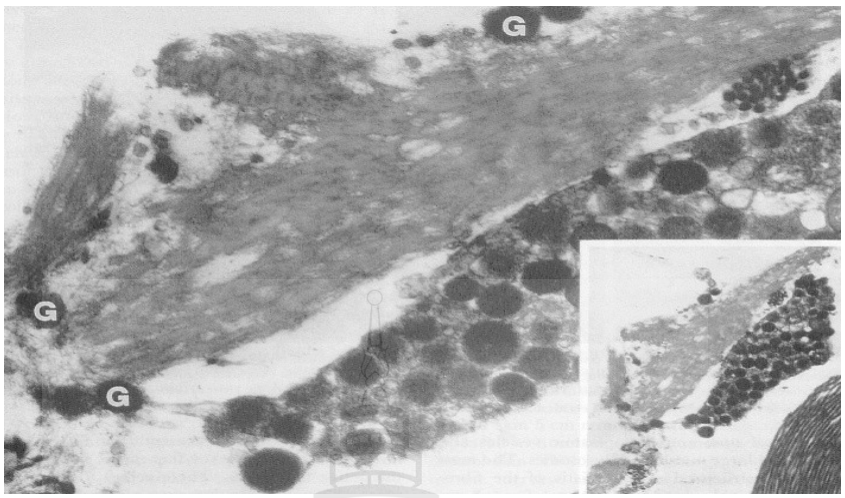
2.1.5 Histological findings

The earliest changes are subclinical, and they are only detectable by electron microscopy. These changes involve mast cell degranulation. The presence of activated macrophages is associated with mid-dermal elastolysis. It has been reported that mast cell activation is associated with elastolysis in actinically affected skin and anetoderma (laxity of the skin due to loss of dermal elasticity) in skin affected by mastocytosis. These findings support the concept that the release of enzymes, possibly elastases from the mast cells, plays a very early and important role in the pathogenesis of striae. Elastases are enzymes that are capable of degrading the elastin molecule within the dermis. However, when lesions initially become visible, fibroblasts become prominent, collagen bundles begin to show structural changes, and the mast cells become absent (Sheu, Yu, & Chang, 1991).



Source Sheu et al. (1991)

Figure 2.4 Early Degradation of Elastic Fibers in Mid-dermis



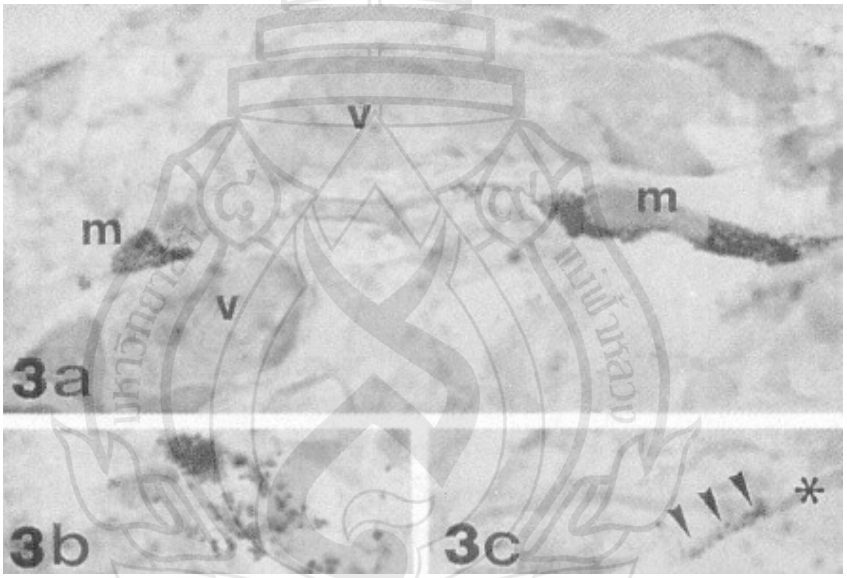
Source Sheu et al. (1991)

Figure 2.5 Naked Granules (G) are Seen between Disintegrated Elastic Fibers.

Source Sheu et al. (1991)

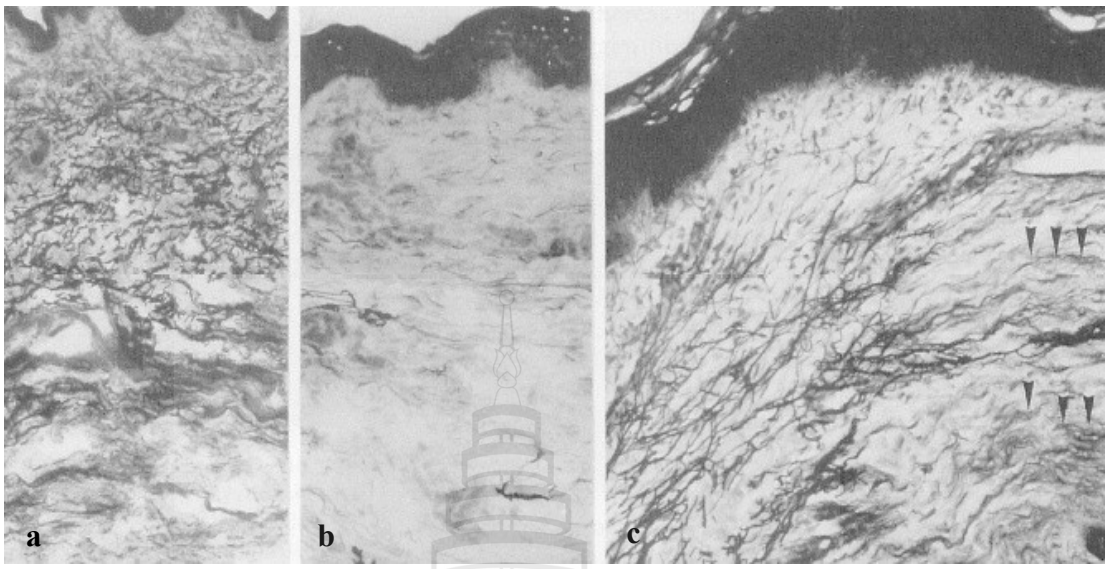
Figure 2.6 An Activated Macrophage (MA) with Two Mast Cells (M1 & M2). These Mast Cells are Undergoing Partial Degranulation (M1) or Cytolysis Secondary to Degranulation (M2).

On light microscopy, the earliest changes in striae rubra consist of dermal edema, perivascular infiltration of lymphocytes, and an increase in the glycosaminoglycan content of the dermis (Singh & Kumar, 2005). Examination of early lesions shows fine elastic fibers predominating throughout the dermis with thick and tortuous fibers present toward the periphery (Tsuji & Sawabe, 1988). An integral component of elastic fibers, fibrillin microfibrils, are found to be reduced in striae rubra (Watson et al., 1998). In contrast, striae alba are characterized by epidermal atrophy, loss of appendages, and a densely packed region of thin eosinophilic collagen bundles aligned horizontal to the surface. From the perspective of light microscopy, later stage lesions are indistinguishable from a dermal scar.



Source Sheu et al. (1991)

Figure 2.7 3a) Granulated Mast Cells (m); Vessels (v) 3b) Degranulated Mast Cells 3c) Secretory Granules (arrowheads) are Closed in Contact with Elastic Fiber (*).



Source Sheu et al. (1991)

Figure 2.8 a) Two-day-old early elevated, erythematous striae demonstrating fragmentation of the elastic fibers throughout the middle and deep reticular dermis. b) One-month-old flat, erythematous striae demonstrating loss of dermal elastic fibers throughout the dermis. c) Four-month-old flat, erythematous striae; new isolated and aggregated fuzzy elastic fibers (arrowheads) scattered throughout the dermis.

2.2 Treatment of Striae Distensae

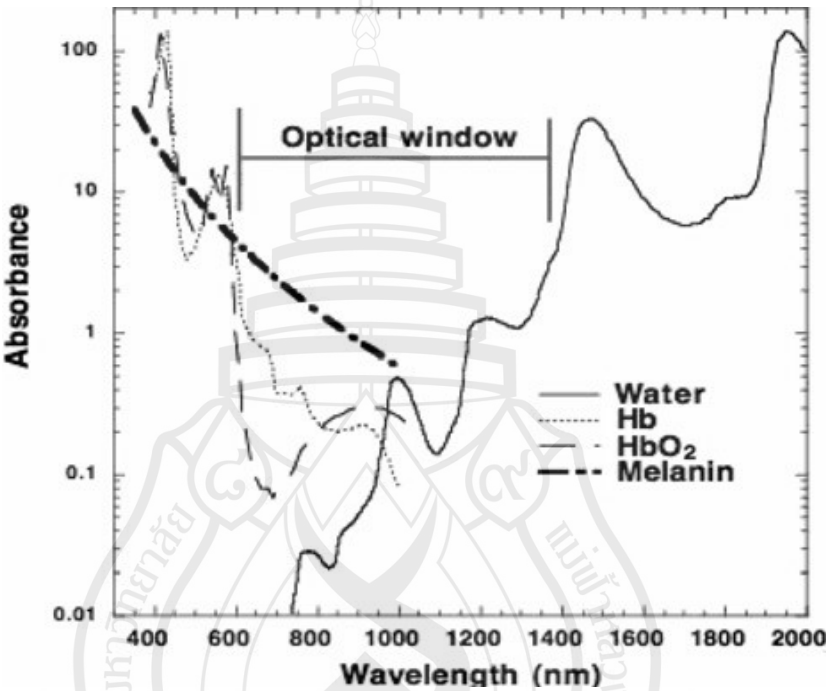
Different therapeutic alternatives have been used for treating striae distensae (Elsaie et al., 2009), although they still remain unsatisfactory (Hidalgo, 2002). Treatment is more effective during striae rubra stage as compared to the striae alba stage. There are two main types of treatment which include physical and chemical methods. Physical methods involve the application of lasers, intense pulsed light, radiofrequency, needling therapy and microdermabrasion on the lesions. Chemical methods involve the use of topical application of creams, chemical peeling and herbal therapy.

2.2.1 Physical methods

2.2.1.1 Application of lasers

1. Pulsed dye laser (585 nm PDL)

The target chromophores of 585 nm PDL laser are hemoglobin and melanin (Figure 2.9).



Source de Felice (2010)

Figure 2.9 Absorption Spectrum of the Three Main Chromophores in Tissues: Water, Hemoglobin and Melanin

The 585 or 595 nm PDL have become the mainstays of therapy for vascular lesions. A previous study demonstrated that 585 nm PDL has a moderate beneficial effect in reducing the degree of erythema in striae rubra among patients with skin types II to IV (Jimenez, Flores, Berman, & Gunja-Smith, 2003). McDaniel demonstrated that the optimal treatment fluence is 3 J/cm^2 using a 10-mm spot size (McDaniel, Ash, & Zukowski, 1996). In contrast, there is no apparent clinical change on striae alba. Total collagen content per gram of dry weight of sampled tissue is

increased in the striae treated with pulsed dye laser (Jimenez et al., 2003). However, PDL laser should be avoided or used with great caution in patients with skin types V to VI, even with low fluences. Therefore another study combined pulsed dye laser with non-ablative radiofrequency (RF) device. RF produces heat when the tissue's electrical resistance converts the electric current into thermal energy deeper within the dermis to avoid hyperpigmentation in skin types IV to VI. The thermage (RF) and pulsed dye laser appear to be an effective treatment for striae distensae (Suh et al., 2007).

2. Excimer laser

The advance technology xenon chloride (308 nm) excimer laser has been used to treat vitiligo and psoriasis. The target tissue for this laser is cellular DNA, especially T cell lymphocytes. The therapy with the 308 nm excimer laser is safe and effective for pigment correction of hypopigmented scars and striae alba (Alexiades-Armenakas, Bernstein, Friedman, & Geronemus, 2004). In another study, 308 nm excimer laser has been shown to temporarily repigment striae alba without improving atrophy (Goldberg, Marmur, Schmults, Hussain, & Phelps, 2005). This laser is also effective for cosmetic improvement (Goldberg, Sarradet, & Hussain, 2003).

3. Copper bromide laser

The copper bromide laser emits a wavelength in the range of 511 and 577 nm. The target chromophores are hemoglobin and melanin. One study treated 15 patients with different stretch marks on different areas of the body. This was achieved by exposing them to laser settings of 4 J/cm^2 for striae on the breast in women or 8 J/cm^2 for striae on other parts of the body. The study concluded that copper bromide laser is effective in decreasing the size of the striae distensae. However, the results with this laser still remain contradictory. Although one certain thing is that this laser can greatly improve scarring, especially in the remodeling and re-epithelization phases. This is an encouragement for the pursuit of striae reduction in further trials (Longo, Postiglione, Marangoni, & Melato, 2003).

4. Non-ablative 1450 nm diode laser

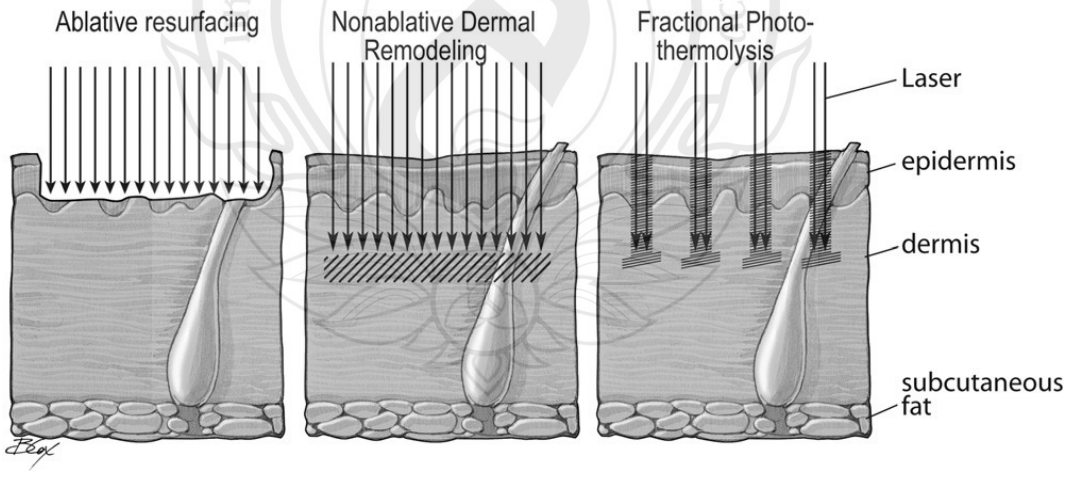
The target chromophore of 1450 nm diode laser is water. It has been shown to improve atrophic scars. However, this laser is not useful in the treatment of striae in patients with skin types IV to VI because it is associated with significant post inflammatory hyperpigmentation (PIH) (Tay, Kwok, & Tan, 2006).

5. 1064 nm Nd:YAG laser

The target chromophores of 1064 nm long pulsed Nd:YAG laser are melanin and water. In addition, this laser has a strong attraction to vascular targets (Sadick, 2003). The laser has demonstrated an increase in dermal collagen when used in the non-ablative treatment of facial wrinkles (Trelles et al., 2005). Furthermore, the 1064 nm long pulsed Nd:YAG laser is safe and effective in the treatment of immature striae (Goldman, Rossato, & Prati, 2008).

6. Fractional photothermolysis

The concept of fractional photothermolysis employs an array of small laser beams to create many microscopic areas of thermal necrosis within the skin called microscopic treatment zones (MTZ). They promote collagen synthesis around adjacent normal tissue (Meduri, 2007).



Source Meduri (2007)

Figure 2.10 Fractional Photothermolysis Creates Microscopic Treatment Zones of Damage in the Epidermis and Dermis.

There are ablative and non-ablative fractional photothermolysis. For example, 10,600 nm Carbon dioxide (CO_2) is an ablative fractional laser, and 1550 nm Erbium-glass is a non-ablative fractional laser. The target chromophore is water. Treatment of striae distensae with fractional photothermolysis is effective because no significant side effects are experienced. Treatment outcomes are better in patients with striae alba than in those with striae rubra (Bak et al., 2009). Similar results are observed in Asian patients with striae alba (Kim et al., 2008).

2.2.1.2 Intense pulsed light (IPL)

Intense pulsed light is characterized by a noncoherent, nonlaser, filtered beam of light, with a broadband spectrum (515-1200 nm). The light source of these devices emits a visible polychromatic pulsed light of high intensity. Its efficacy has been reported recently in the treatment of photodamaged facial skin. It is known to promote the production of neocollagen while enhancing the ordering of elastic fibers (Roenigk & Roenigk, 1996). Striae alba improve clinically and microscopically after treatment with IPL (Hernandez-Perez, Colombo-Charrier, & Valencia-Ibiett, 2002).

Table 2.1 Summary of Different Lasers and Light Sources Treatments for Stretch Marks

Type of laser	Effectiveness in striae distensae
Pulsed dye laser	Demonstrated to be effective only for the immature stage of striae (striae rubra); works by targeting the vascular element. Not effective in darker skin and associated with pregnancy-induced hypertension. When combined with radiofrequency, it shows a more promising response even on striae alba.
Copper bromide laser	Mild to moderate effect in one study in patients with skin types II and III; no histological analysis was carried out. Needs further evaluation.
1450 nm Diode laser	Not useful in skin types IV to VI and associated with many complications.

Table 2.1 (continued)

Type of laser	Effectiveness in striae distensae
1064 Neodymium-doped yttrium aluminum garnet laser	Targets immature striae; satisfactory results in the few studies conducted so far.
Excimer laser	Although only repigments temporarily and does not have an effect on atrophy; a good safety profile.
Intense pulsed light	A good alternative that has been shown to be an effective tool in striae alba; although with a high incidence of pregnancy-induced hypertension.
Fractional photothermolysis	Few studies conducted, although all reported efficacy in immature and mature striae while demonstrating an increase in the number of collagen and elastic fibers; a good safety profile.

Source Elsaie et al. (2009)

2.2.1.3 Radiofrequency (RF)

Non-ablative radiofrequency device was developed especially for tightening deeper dermal structures without epidermal damage. This new device is capable of delivering higher energy fluences through skin to a greater volume of dermal tissue than non-ablative lasers with no epidermal injury. The study demonstrated that there is no significant difference in the striae surface smoothness resulting from its use. RF seems to be an alternative treatment for striae (Manuskiatti, Boonthaweeyuwat, & Varothai, 2009).

2.2.1.4 Needling therapy

Treatment with needling therapy might be able to promote the removal of old damaged collagen and induce more collagen growth beneath the epidermis. Puncturing the skin multiple times in acne scars increases the amount of collagen and elastin deposition (Fabbrocini, Fardella, Monfrecola, Proietti, & Innocenzi, 2009).

The pilot study demonstrated that disk microneedle therapy system (DTS) can be effectively and safely used in the treatment of striae distensae (Park, Kim, Kim, Kim, & Kim, 2012).

2.2.1.5 Microdermabrasion

Microdermabrasion or particle resurfacing is a minimally invasive procedure that relies on an abrasive component, usually aluminum oxide crystals and a vacuum component. Abdel-Latif found that there was improvement in the appearance of striae in 50% of cases. More improvement was obtained in striae rubra than striae alba. Up-regulated type I procollagen α1 mRNA expression was found in the microdermabrasion treated striae compared to untreated striae (Abdel-Latif & Elbendary, 2008).

2.2.2 Chemical methods

Chemical methods involve the use of topical preparations such as tretinoin, hydrant creams, chemical peeling and herbal therapy.

2.2.2.1 Tretinoin

Tretinoin (Retinoic acid) is a carboxylic derivative of vitamin A. It can restore collagen type I formation in photodamaged skin (Griffiths et al., 1993). Earlier studies on topical tretinoin therapy for management of striae have yielded variable results. However, the majority of the patients in these studies were treated for stretch marks that had already evolved into white, atrophic, scar-like lesions (Elson, 1990). A study demonstrated that low dose 0.025% tretinoin is ineffective in treating striae distensae (Pribanich, Simpson, Held, Yarbrough, & White, 1994). More recently, tretinoin has been shown to improve the clinical appearance of stretch marks during the active stage (striae rubra), but not much during the mature stage (striae alba). In the same study, 22 patients applied 0.1% tretinoin (n = 10) or the placebo (n = 12) daily for six months to the affected areas. Targeted stretch marks in patients treated with tretinoin had a decrease in mean length and width of 14% and 8% respectively, compared with an increase of 10% and 24% respectively in patients who received the placebo. The biopsy of lesions revealed that there were no significant changes in both collagen and elastic fibers (Kang, 1998). Rangel conducted an open multicenter study in 20 Mexican women with stretch marks after pregnancy. The subjects were applied

0.1% tretinoin daily for three months in the abdominal area. The target lesions decreased by 20% in length and 23% in width compared to their pretreatment dimensions. The results demonstrated the efficacy of tretinoin in treating stretch marks after pregnancy (Rangel, Arias, Garcia, & Lopez-Padilla, 2001).

2.2.2.2 Hydrant creams

1. Trofolastin

In one study involving 80 pregnant women, the preventive effect of massage with Trofolastin on the development of stretch marks was studied. Trofolastin is a cream containing *Centella asiatica* extract, α-tocopherol and collagen-elastin hydrolysates. Forty-one subjects were treated with Trofolastin, while 39 subjects were treated with the placebo. Results showed that 34% of the treated group and 56% of the placebo group developed striae gravidarum. The absolute reduction risk was 22% in preventing striae gravidarum (ARR = 0.22, NNT = 4.55) (Mallol, Belda, Costa, Noval, & Sola, 1991). It is not possible to assess which of the components of the cream is active, as the constituents were not tested individually in this study. It is also possible that there is synergism between the components of the cream. Nonetheless, the active constituent of *Centella asiatica*, known as asiaticoside, has been found to promote the synthesis of collagen and fibronectin in cultured fibroblasts (Tenni et al., 1988). Therefore it is possible that asiaticoside is responsible for the positive effect of the cream.

2. Verum

Another study of 50 pregnant women, although lacking a placebo, examined a verum cream containing vitamin E, panthenol, hyaluronic acid, elastin and menthol. Twenty-four subjects were treated with verum cream, while 26 subjects were in the control group. Only one-third of the subjects developed striae gravidarum in the treated group, while two-third of the subjects developed striae gravidarum in the untreated control group. The results suggested that the product could be helpful, although the trial had no placebo and may show the benefit of massage alone (Wierrani, Kozak, Schramm, & Grunberger, 1992).

3. Alphastria

Alphastria is a cream composed of hyaluronic acid, allantoin, vitamin A, vitamin E and dexpanthenol. “Alpha” in Greek means ‘‘without’’, whereas “stria” in Latin means ‘‘lines’’. Hyaluronic acid may be an active ingredient. Hyaluronic acid is an organic substance found in human skin and is the main constituent of the cream. The hyaluronic content stimulates fibroblast activity and collagen production. However, a higher amount of hyaluronic acid inhibits collagen synthesis as well as promotes elastin synthesis (Shah, Recktenwall-Work, & Anseth, 2008). Only one study was conducted to demonstrate the efficacy and safety of the cream. Thirty pregnant women were treated with Alphastria, while another 30 pregnant women were treated with the placebo. Three subjects in the Alphastria group and 21 subjects in the placebo group developed striae gravidarum. The study concluded that Alphastria reduced the incidence of striae gravidarum (de Buman, Walther, & de Weck, 1987). However, this study did not identify the possible active ingredient.

4. Mederma

Mederma is a cream composed of onion extract, *Centella asiatica* and hyaluronic acid. Onion extract has been shown to demonstrate anti-inflammatory properties in vitro. This is due to the presence of a flavonoid known as cepanes (Dorsch, Schneider, Bayer, Breu, & Wagner, 1990). Onion extract also contains sulfur in the form of thiosulfinates accounting for anti-infective properties in vitro (Dorsch, et al., 1990), fibrinolytic effects (Augusti, 1996), and antimicrobial activity against Gram-positive bacteria (Dankert, Tromp, de Vries, & Klasen, 1979; Zohri, Abdel-Gawad, & Saber, 1995). A proprietary onion extract gel has been shown to improve the appearance of post-surgical shave excision scars (Draelos, 2008). *Centella asiatica*, also known as Indian pennywort, is widely used in naturopathic medicine for ulcer healing. It contains asiaticoside that has been shown to increase type I collagen production which enhances wound healing and scar maturation (Draelos et al., 2010). Hyaluronic acid is a moisturizing emollient vehicle and a potent humectant aiding in the water holding capacity of the skin. Previous studies have demonstrated its wound healing potential (Chrit et al., 2007). The results demonstrated that mederma cream significantly improves the appearance of striae rubra lesions. The subjects were well tolerated with no adverse events during the study (Draelos et al., 2010).

2.2.2.3 Chemical peeling

1. Glycolic acid (GA)

Glycolic acid is an alpha hydroxyl acid. Although there are several reports on the clinical effects of glycolic acid in rejuvenation, peeling and photoaging; no data regarding the effectiveness of glycolic acid to prevent stretch marks could be found in the scientific literature. No epidemiological study on the use of glycolic acid in pregnant women has been published. There was however a study comparing topical 20% glycolic acid and 0.05% tretinoin with 20% glycolic acid and 10% L-ascorbic acid. The results demonstrated that both regimens improve the appearance of striae alba. These topical therapy regimens did not produce significant irritation in the subjects (Ash et al., 1998). The precise mechanism of glycolic acid is still unknown because the biological effects of glycolic acid on cells have not been fully studied. However, glycolic acid has been reported to stimulate collagen production via fibroblasts and to increase their proliferation in vivo and in vitro (Kim, Park, Kim, Won, & Maibach, 1998; Okano et al., 2003). This mechanism can be useful for treatment of stretch marks, but further investigations and studies are required to prove such theory.

2. Trichloroacetic acid (TCA)

Trichloroacetic acid (10%-35%) has been used for many years, and it is safe in low concentrations. It has a tendency to develop scars at higher concentrations (TCA $\geq$ 50%). In earlier reports, TCA was used in stretch marks, although there is a lack of clarity and absence of data for assessment. A study of using 15%-20% low concentrations TCA and performing monthly chemo-exfoliation showed improvement in texture and color of stretch marks (Obagi, Obagi, Alaiti, & Stevens, 1999).

2.2.2.4 Herbal therapy

1. Bio-Oil™

Bio-Oil™ is an oil-based cosmetic formulation. It contains a mixture of potentially active ingredients in a mineral oil, isopropyl myristate and cetearyl ethylhexanoate base. The active ingredients include retinyl palmitate, tocopherol acetate and glycine soja that are known to play a role in skin improvement. Other ingredients in Bio-Oil™ are *Lavandula augustifolia* (astringent and antiseptic), *Rosmarinus officinalis* (soothing and antiseptic), *Calendula officinalis* (regenerative),

and bisabolol (anti-inflammatory). In South Africa, Bio-Oil™ has been produced and marketed since 1987. Consumers found that the product improved the appearance of uneven skin pigmentation, striae and scars. A study was conducted among 20 healthy Caucasian women with bilateral abdominal striae. The women used Bio-Oil™ on one side of their abdomen and normal moisturizer on the other side twice daily for 12 weeks. The results demonstrated the Bio-Oil™ significantly improved the appearance of striae on the treated side of the abdomen as evaluated by both subjective and objective assessments. This study showed that it is possible to improve the appearance of striae with the topical application of a relatively low-cost and non-medicinal product (Summers, 2009).

2. Cocoa butter lotion

Cocoa butter is a natural fat derived from cocoa beans (*Theobroma cacao*). It is commonly used in many cultures. It is a commercially available lotion containing cocoa butter and tocopheryl acetate (vitamin E). It has moisturizing properties. Many women believe that the application of cocoa butter to the skin helps to prevent the development of striae gravidarum. Some physicians and midwives advise their patients to use cocoa butter before, during or even after pregnancy for prevention or treatment of striae gravidarum. A study on cocoa butter lotion involved 210 nulliparous women with gestational ages between 12 and 18 weeks. Only 175 (83%) completed the study. Ninety-one women were treated with cocoa butter lotion, while 84 women were treated with the placebo. The subjects were instructed to apply the lotion once daily until the time of delivery. There was no difference in the incidence of striae gravidarum (45.1% versus 48.8%; $p = 0.730$) or the severity of striae gravidarum between cases and controls. However, this study lacked the reliability of compliance (Osman et al., 2008). Another similar study conducted in 300 nulliparous women; 150 women received 25% cocoa butter cream, while 150 women received the placebo. The placebo cream contained water, glycerin (skin conditioner), distearyldimonium chloride (skin conditioner), isopropyl palmitate (emollient), cetearyl alcohol (stabilizer), propylene glycol isostearate (emollient), PPG-15 stearyl ether (1-octadecoxypropan-2-ol) emollient, hydrolyzed collagen, hydrolyzed elastin, tocopheryl acetate (vitamin E), dimethicone (skin conditioner). The women were followed up from 16 weeks of pregnancy to delivery to assess the

development of striae gravidarum. Striae gravidarum developed in 44% of subjects using cocoa butter cream compared with 55% of those using placebo; the difference was not significant (χ^2 = 2.8, df (1), p = 0.09) (Buchanan, Fletcher, & Reid, 2010). This study had confounding factors from active ingredients in the case and the control groups. Therefore it could not be ruled out that any of the ingredients presented in the placebo had prophylactic properties.

3. Almond oil

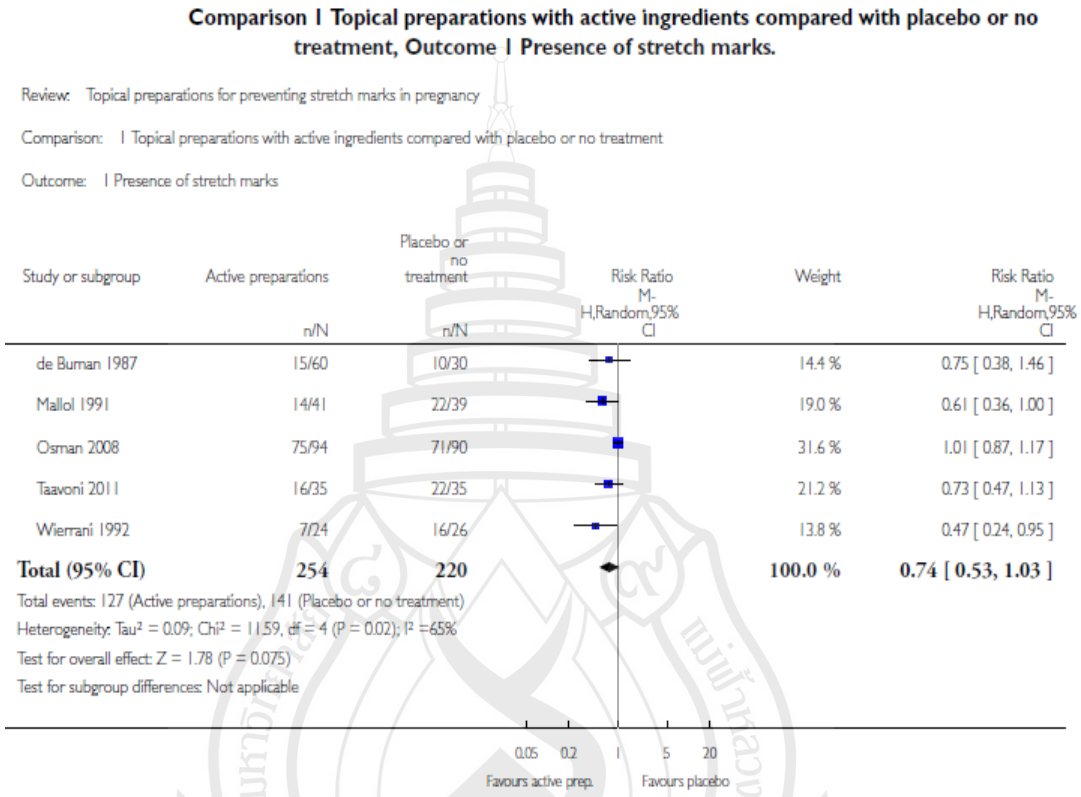
In one study involving 141 primiparous women with gestational age of 19 weeks, the effect of bitter almond oil on preventing striae gravidarum was studied. The subjects were divided into three groups: the primiparous women who applied bitter almond oil with massage (n = 47), who merely applied bitter almond oil (n = 48) and who were in the control group (n = 46). The frequency of striae gravidarum was 20% among the women who applied bitter almond oil with massage, 38.8% among those who merely applied bitter almond oil and 41.2% in the control group. The frequency of striae gravidarum was also found to be lower in the group who applied almond oil with massage compared to the others ($p < 0.05$) (Timur Tashan & Kafkasli, 2012). It was found that a 15 minute massage applied with almond oil during pregnancy reduced the development of striae gravidarum, but using bitter almond oil had no effect on this in itself. It is recommended that pregnant women be informed about the positive effects of massaging applied with almond oil early during their pregnancy. However, this study lacked the placebo group; therefore placebo effect may occur in the intervention group.

4. Olive oil

The topical application of olive oil to prevent striae gravidarum during pregnancy has yielded controversial results. In a study by Poidevin and Sydney in Adelaide University in Australia, 60% of the olive oil users and 55% of the controls developed striae gravidarum (Poidevin, 1959). In contrast, a study of 74 primiparous women showed that the prophylactic use of olive oil to massage the abdomen was associated with a low incidence of striae gravidarum. The incidence of striae gravidarum was 26% in the olive oil users and 61% in the controls (Davey, 1972). Another study involved 70 nulliparous women with gestational ages between 18 and 20 weeks. The intervention group was instructed to apply olive oil on their abdomen

twice daily without massaging for eight weeks. The rate of striae occurrence at the end of the second trimester of pregnancy was 45.7% in the intervention group and 62.9% in the control group. The results showed no significant difference (Taavoni, Soltanipour, Haghani, Ansarian, & Kheirkhah, 2011). A subsequent study involved 100 nulliparous women with gestational ages between 18 and 20 weeks. Fifty women were enrolled and randomly allocated to each study group. The intervention group was instructed to apply 1 cc of olive oil on the abdomen twice daily in a gentle manner without massaging until the time of delivery. The control group did not receive any cream or oil during the study. The results demonstrated that olive oil reduced the incidence of severe striae gravidarum. The frequency of severe striae gravidarum was 6% in the olive oil group and 14% in the control group. The incidence of striae gravidarum was 36% in the olive oil group and 40% in the control group. However, the use of olive oil did not significantly reduce the incidence and severity of striae gravidarum (Soltanipoor et al., 2012). One study compared the effects of Saj cream and olive oil on striae gravidarum. This study involved 105 nulliparous women with gestational ages between 18 and 20 weeks. The subjects were randomized into three groups. Two intervention groups applied Saj cream (n = 30) or olive oil (n = 30), and the control group (n = 30) did not apply any cream. Striae gravidarum developed 16.7% in Saj cream users, 40% in olive oil users and 56% in the control group. There was a significant difference between the intervention groups and the control group ($p < 0.006$) (Taavoni, Soltanipour, Haghani, & Kheirkhah, 2012). The previous study by Davey lacked a proper method in randomized allocation in each group. However, recent studies by Taavoni and Soltanipoor were randomized controlled trials conducted to get the best results regarding the prevention of striae gravidarum and controlling their severity. However, these studies lacked the placebo intervention. In conclusion, we could not conclude the preventive effect on striae gravidarum.

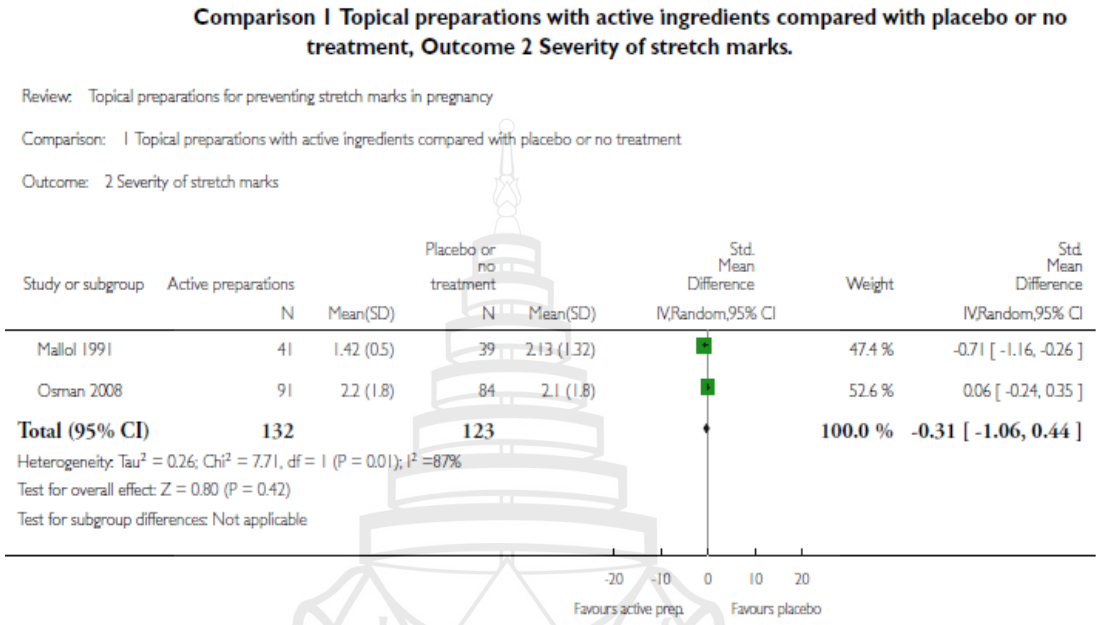
A meta-analysis review of topical preparations for prevention of stretch marks in pregnancy demonstrated no significant benefit (Figure 2.11) (Brennan, Young, & Devane, 2012).



Source Brennan et al. (2012)

Figure 2.11 The Presence of Stretch Marks in Topical Preparations with Active Ingredients Compared with Placebo or No Treatment

Another study demonstrated no significance in reducing the severity of striae gravidarum (Figure 2.12) (Brennan et al., 2012).



Source Brennan et al. (2012)

Figure 2.12 The Severity of Stretch Marks in Topical Preparations with Active Ingredients Compared with Placebo or No Treatment

We considered that the use of olive oil may have effect on preventing severe striae gravidarum, but the studies by Taavoni et al. (2011) and Soltanipoor et al. (2012) lacked the placebo intervention. The interpretation of studies may have bias due to non-placebo effect. Olive oil is a rich source of vitamin E (Haytowitz et al., 2012). We assumed that the vitamin E in olive oil may be an active ingredient due to the following reasons.

1. Antioxidant effect (Sen, Khanna, & Roy, 2006)

The earliest striae changes involve mast cell degranulation. The presence of activated macrophages is associated with mid-dermal elastolysis (Sheu, Yu, & Chang, 1991). The macrophages may produce hydrogen peroxide for elastolysis (Karastathis, 2011). Vitamin E has an antioxidant effect. Therefore vitamin E may prevent hydrogen peroxide that is produced by macrophages. The consequence of this action is to inhibit elastolysis during early phase of striae development.

2. Modulation of collagen synthesis

A number of studies suggested that fibroblasts play an important role in the pathogenesis of striae. Examination of expression of four different genes encoding for the proteins procollagen I and III, elastin and fibronectin, by extracting the RNA from striae distensae lesions, leads to the demonstration that the level of expression of the four proteins is reduced compared to the level of expression in normal tissue (Lee, Rho, Jang, Suh, & Song, 1994). Fibroblast cells are principally responsible for synthesizing these matrix proteins, but they also have the potential of tissue contraction particularly involved in the wound healing (Gabbiani, Ryan, & Majne, 1971). According to a previous study, in an unstimulated state of fibroblasts, the function of vitamin E inhibited α_1 (I) gene expression (Houglum, Brenner, & Chojkier, 1991). In contrast, in a stimulated state of fibroblasts by hydrogen peroxide, the function of vitamin E increased total collagen synthesis and up-regulation of *COL I* and *COL III* genes (Makpol et al., 2011).

2.3 Vitamin E

2.3.1 Dietary sources of vitamin E

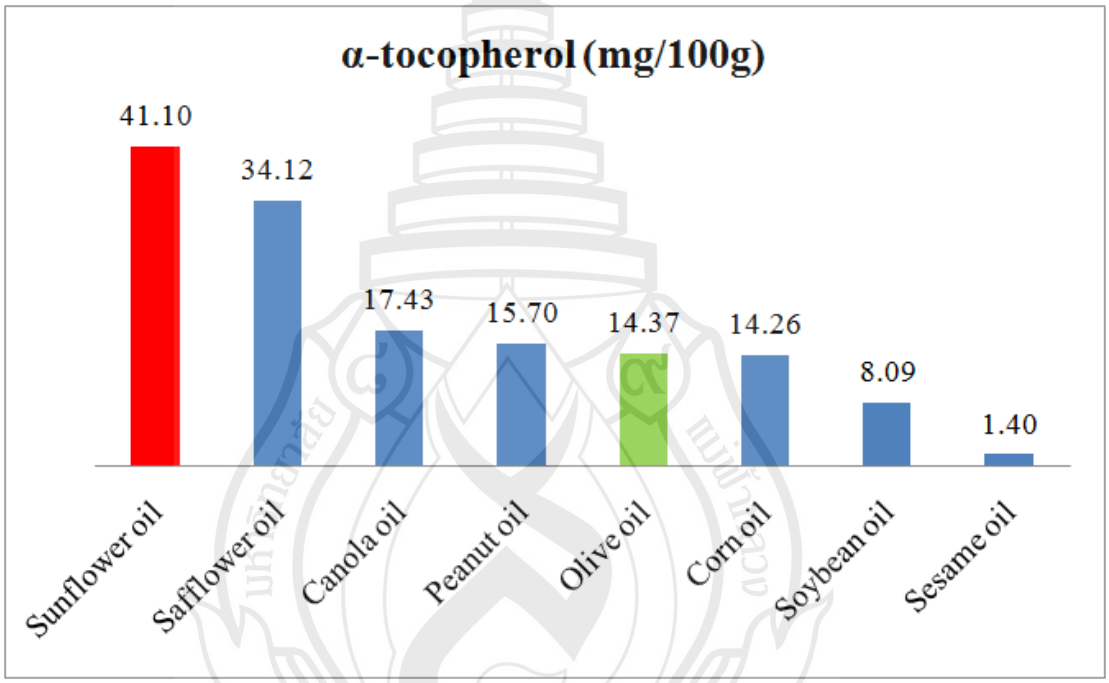
Vitamin E can be found most abundantly in vegetable oils.

Table 2.2 Vitamin E (α-tocopherol) (mg) Content of Selected Foods per Common Measure

Vegetable oils	Weight (g)	Common measure	Content per measure
Oil, canola	14	1 tbsp	2.44
Oil, corn, industrial and retail, all purpose salad or cooking	13.6	1 tbsp	1.94
Oil, olive, salad or cooking	13.5	1 tbsp	1.94
Oil, peanut, salad or cooking	13.5	1 tbsp	2.12
Oil, safflower, salad or cooking, high oleic (primary safflower oil of commerce)	13.6	1 tbsp	4.64
Oil, sesame, salad or cooking	13.6	1 tbsp	0.19
Oil, soybean, salad or cooking, (partially hydrogenated)	13.6	1 tbsp	1.10
Oil, soybean, salad or cooking, (partially hydrogenated) and cottonseed	13.6	1 tbsp	1.65
Oil, sunflower, linoleic, (approx. 65%)	13.6	1 tbsp	5.59

Source Haytowitz et al. (2012)

All the vegetable oils contain different proportions of the compounds collectively known as vitamin E (Table 2.2). According to the US Department of Agriculture (USDA), the sunflower oil has the highest amount of α-tocopherol among the vegetable oils with a value of 41.10 mg/100g (Figure 2.13). The amount of α-tocopherol in safflower oil, canola oil, peanut oil, olive oil, corn oil, soybean oil and sesame oil is 34.12, 17.43, 15.70, 14.37, 14.26, 8.09 and 1.40 mg/100g respectively (Haytowitz et al., 2012).



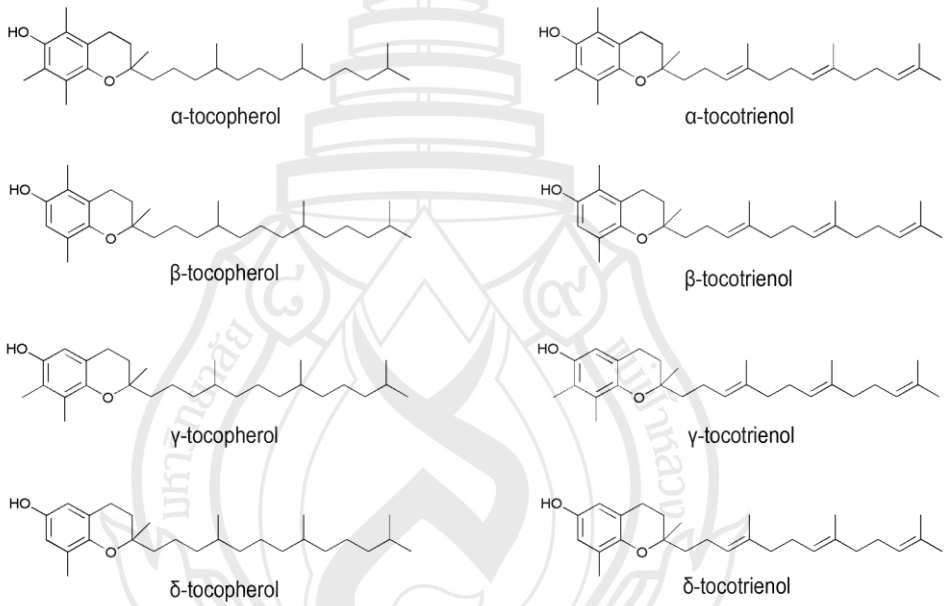
Source Haytowitz et al. (2012)

Figure 2.13 α-tocopherol (mg/100g)

2.3.2 Structure of vitamin E

Vitamin E comprises eight different chemical compounds known as tocopherols and tocotrienols (Sen et al., 2006). Four tocopherols, namely α-tocopherol, β-tocopherol, γ-tocopherol, δ-tocopherol, and four tocotrienols, α-tocotrienol, β-tocotrienol, γ-tocotrienol, δ-tocotrienol, are known collectively as vitamin E (Figure 2.14). The difference between these compounds is the presence of three unsaturations on the 16-

carbon phytyl chain in tocotrienols which are absent in tocopherols. The position and the amount of methyl substituents on the chromane ring serve to differentiate between the α, β, γ and δ forms. Most of the research on vitamin E has been focused on tocopherols (particularly α-tocopherol). However, tocotrienols have been found useful as neuroprotective, hypocholesterolemic, antioxidant and anti-cancer agents (Sen et al., 2006). Tocotrienols are even more potent antioxidants than tocopherols (Serbinova & Packer, 1994), and because of their unsaturation they are able to cross and diffuse more easily into fatty tissues (Suzuki et al., 1993).



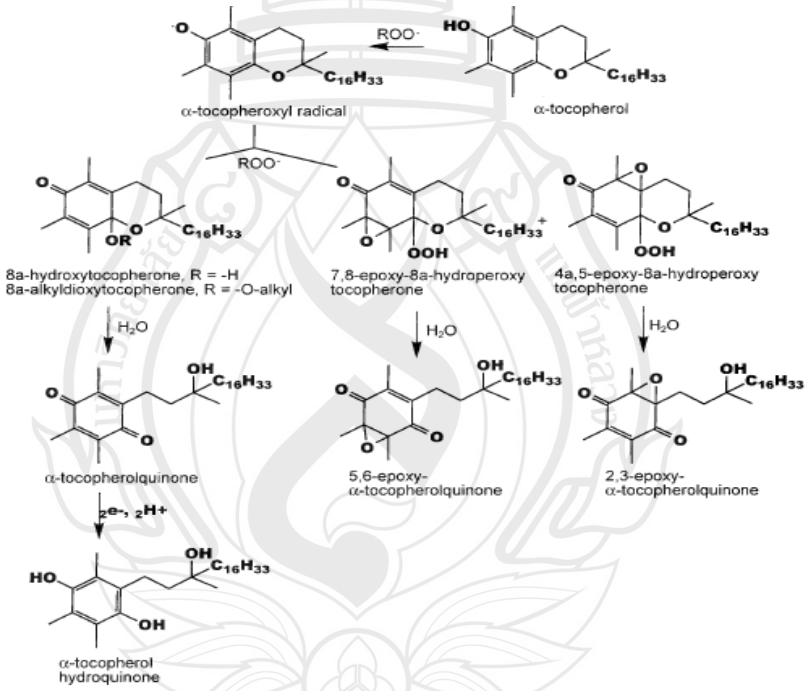
Source Sen et al. (2006)

Figure 2.14 Chemical Structures of the Eight Constituents Collectively Known as Vitamin E

2.3.3 Functions of vitamin E

2.3.3.1 Antioxidant functions

Vitamin E functions as a chain-breaking antioxidant that prevents the propagation of free radical reactions, especially in biological membranes. For example, Ham and Liebler demonstrated the induction of lipid peroxidation by perfused male Sprague-Dawley rat livers with 2mM tert-butylhydroperoxide (t-BuOOH)[2] for 10 minutes. t-BuOOH induced oxidation of α-tocopherol to α-tocopherol quinone, α-tocopherol hydroquinone, 2,3-epoxy-α-tocopherol quinone, and 5,6-epoxy-α-tocopherol quinone (Figure 2.15). Furthermore, vitamin E can prevent mitochondrial dysfunction in severe oxidative stress conditions (Ham & Liebler, 1997).



Source Liebler, Burr, Philips, & Ham (1996)

Figure 2.15 Reactions of α-tocopherol with Peroxyl Radicals

2.3.3.2 Non-antioxidant functions

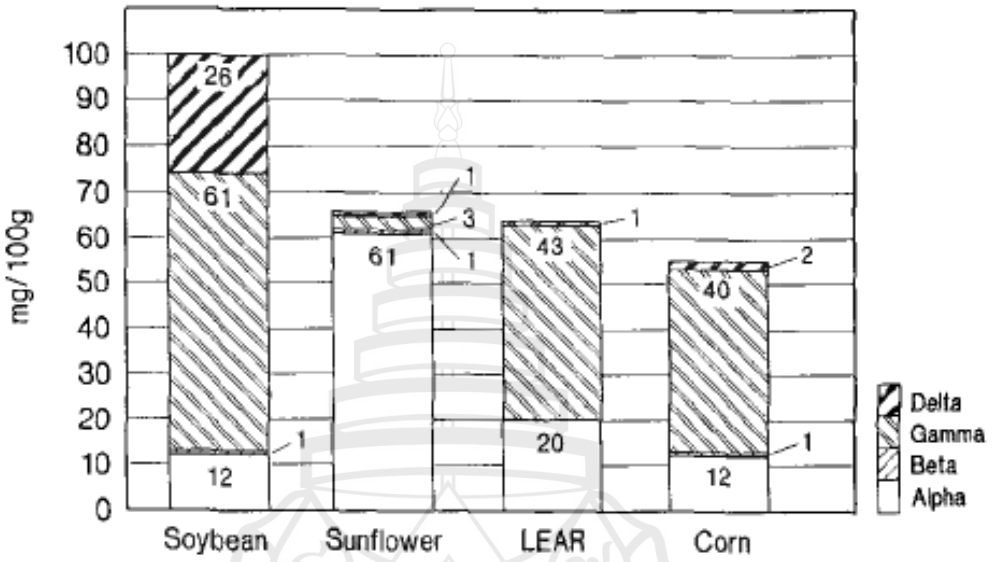
1. Cellular signaling

The role of vitamin E in cellular signaling, especially in relation to protein kinase C, has been studied by Azzi's group (Azzi et al., 1998). α-tocopherol inhibits smooth muscle cell proliferation (Boscoboinik, Szewczyk, Hensey, & Azzi, 1991), decreases protein kinase C activity (Boscoboinik, Szewczyk, & Azzi, 1991), increases phosphoprotein phosphatase 2A activity (Ricciarelli et al., 1998), and controls expression of the α-tropomyosin gene. The inhibition mechanism of protein kinase C activity is not due directly to the antioxidant capacity of α-tocopherol. It requires the integration of α-tocopherol into a membrane structure, and also direct interaction between α-tocopherol and protein kinase C in the cell membrane (Cachia et al., 1998). α-tocopherol involves in modulating atherogenesis (Chan, 1998). Vitamin E enrichment of endothelial cells down-regulates the expression of intercellular cell adhesion protein and vascular cell adhesion molecule-1, therefore reducing the oxidized LDL-induced adhesion of white cells to the endothelium (Cominacini et al., 1997). α-tocopherol can also regulate the arachidonic acid cascade pathways, and its effect is not always shared by other vitamin E forms (Chan, 1998). Vitamin E up-regulates the activities of cytosolic phospholipase A2 (Chan et al., 1998; Tran, Wong, Lee, Chan, & Choy, 1996) and cyclooxygenase (Chan et al., 1998). The enhanced activity of these two rate-limiting enzymes in the arachidonic acid cascade provides a mechanism for the observation that vitamin E dose dependently enhances release of prostacyclin, a potent vasodilator and inhibitor of platelet aggregation (Chan & Leith, 1981; Gilbert, Zebrowski, & Chan, 1983; Pyke & Chan, 1990; Szczeklik, Gryglewski, Domagala, Dworski, & Basista, 1985; Tran & Chan, 1990).

2. Infertility

Vitamin E prevents loss of spermatogenesis in male rats. It also prevents the failure to retain zygotes in female rats (Evans & Bishop, 1922). Due to the synergistic effect of vitamin E and selenium, the mechanism allows the protection of biomembranes from oxidative attack. This process prevents the functional and structural alterations of spermatozoa (Wu, Oldfield, Whanger, & Weswig, 1973).

In conclusion, the review of vitamin E may benefit in understanding biochemical functions in the cell biology. One study had shown the ratio of α-tocopherol in vegetable oils (Figure 2.16).



Source Warner and Mounts (1990)

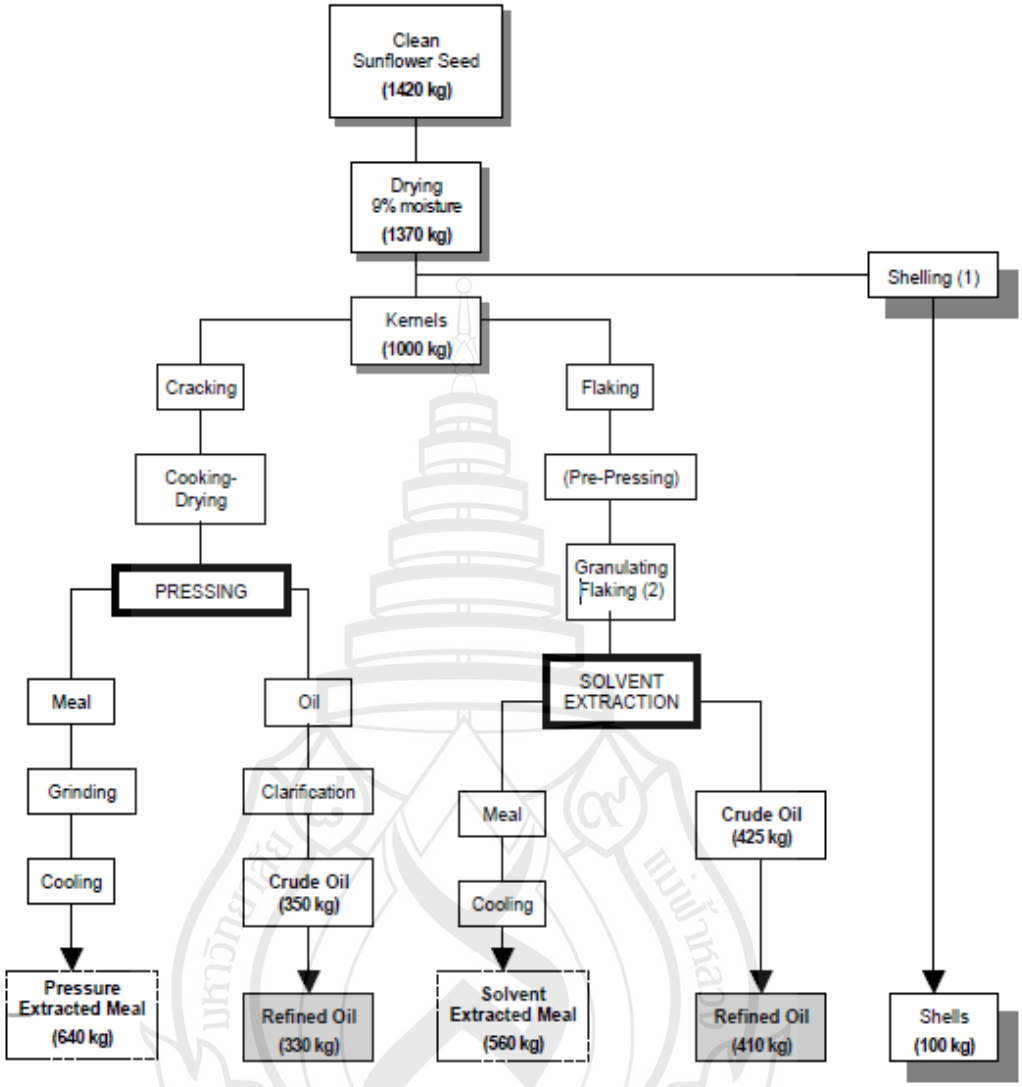
Figure 2.16 The Ratio of Different Forms of Tocopherols (mg/100g)

Warner reported the analysis of tocopherols and phytosterols in vegetable oils by HPLC with evaporative light-scattering detection. The study found that the ratio of α-tocopherol to other forms is the highest in sunflower oil with a value of 61 mg/100g. α-tocopherol is the most biologically active form of vitamin E (Warner & Mounts, 1990).

2.4 Sunflower Oil

Sunflowers (*Helianthus annuus*) are native American wild flowers, belonging to the family Compositae. Talking in terms of nutrition, the first evidence of sunflower usage as food in the United States was done by Indians at Roanoke Island, North Carolina in 1586. It was also used later in 1615 by New England colonists as hair oil (Robertson & Burns, 1975). Since that time, sunflowers have established their own economic base in the world agricultural market. In the 1830s, Russia developed a feasible process for oil extraction from sunflower seed and began to utilize it as a field crop. The first commercial use of the sunflower crop in the US was as silage feed for poultry. In 1926, the Missouri Sunflower Growers' Association participated in what is likely the first processing of sunflower seed into oil (Blamey, Zollinger, & Schneiter, 1997). Sunflower was imported and planted in Thailand by the French during the reign of King Narai in 1665 (Siam Society, 1934).

There are two methods for crude oil extraction which include mechanical press and chemical extraction. When compared, the yield of mechanical press is lower (80%) as compared to chemical extraction method (99%) (Food and Agriculture Organization of the United Nations [FAO], 2010). After obtaining crude oil, the next is refining process. The refining process involves degumming, neutralizing, drying, bleaching, deodorizing and dewaxing while heating over 240º C (Wagner, Auer, & Elmadfa, 2000). The temperatures over 150º C destroy the proteins and natural vitamin E in both the oil and the meal (Rudy & Senkowski, 1974). The total tocopherol losses during the refining process accounted on average for 41% (Gogolewski, Nogala-Kalucka, & Szeliga, 2000; Kilcast & Subramaniam, 2000). In contrast, cold pressed method utilizes lower temperatures (50º C to 70º C). This process does not damage the oil and the meal significantly and preserve vitamin E in the oil (Wroniak, Krygier, & Kaczmarczyk, 2008). The diagram of oil extraction is shown in Figure 2.17 (FAO, 2010).



Source FAO (2010)

Figure 2.17 The Process for Sunflower Oil Extraction

So far, no study has been conducted regarding the application of sunflower oil for the prevention of striae gravidarum. To attain the maximum possible concentration of vitamin E for our study, we have used cold pressed sunflower oil.

CHAPTER 3

RESEARCH METHODOLOGY

3.1 Research Design

This was a split-abdomen, randomized, double-blind clinical trial.

3.2 Population and Sample

3.2.1 Population

Nulliparous women between the ages of 18 and 40 years with gestational ages between 16 and 18 weeks were included in this study.

3.2.2 Sample

Nulliparous women between the ages of 18 and 40 years with gestational ages between 16 and 18 weeks, who attended Pranangklao hospital for prenatal care. Participants were willing to participate in the research in order to prevent striae gravidarum and undergo follow up every visit until delivery.

3.2.3 Sample size determination

Calculation of the sample size was performed for studying the incidence and prevention of striae gravidarum with the use of sunflower oil. According to the Bolognia, the incidence of striae gravidarum was approximately 75% (Bolognia et al., 2007). According to another study conducted by using olive oil, the incidence of striae gravidarum was 45.7% in the intervention group and 62.9% in the control group (Taavoni et al., 2011). Therefore the sample size was calculated by using the formula below.

Formula

$$n = \left[\frac{z_{\frac{\alpha}{2}} \sqrt{p_0(1-p_0)} + z_{\beta} \sqrt{p_1(1-p_1)}}{p_1 - p_0} \right]^2$$

Where α = Probability of type I error (2-sided) = 0.05, Z $\alpha/2$ = 1.96

β = Probability of type II error (2-sided) = 0.20, Z_β = 0.8416

p_o = The incidence of unprevented striae gravidarum = 0.75

p_1 = The incidence of prevented striae gravidarum = 0.457

$$n = \frac{[1.96\sqrt{0.75(1-0.75)} + 0.8416\sqrt{0.457(1-0.457)}]^2}{[0.457-0.75]^2}$$

n = 18.73

The sample size was 19 people.

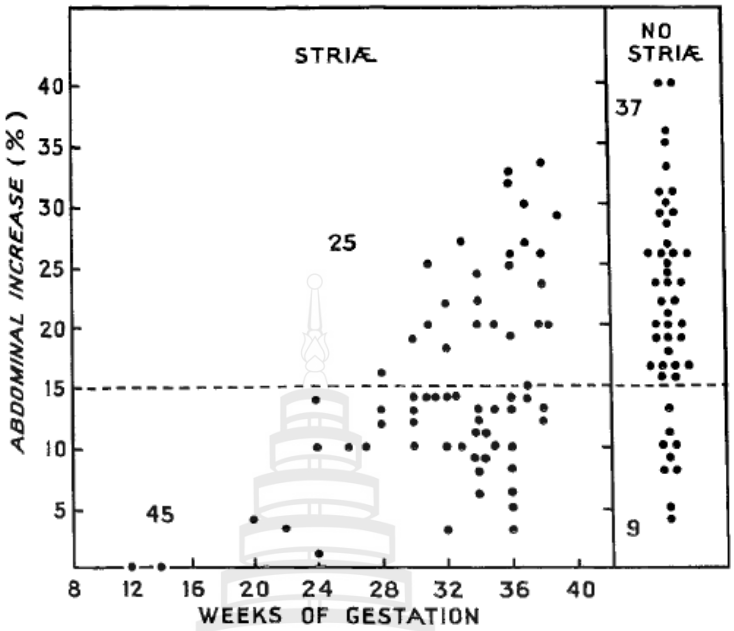
According to the calculation of the sample size above, the number of the sample size was 19 people, but to overcome the difficulty that ensued due to dropout (estimated 30%), the number of the sample size was 25 people.

3.3 Sample Selection

3.3.1 Inclusion criteria

3.3.1.1 Nulliparous women between the ages of 18 and 40 years

3.3.1.2 Gestational ages between 16 and 18 weeks



Source Poidevin (1959)

Figure 3.1 The Relation between Increased Abdominal Girth and the Time of Development of Striae

3.3.1.3 Body mass index (BMI) between 18.5 and 25 kg/m^2

3.3.1.4 Abstinence from topical or oral steroids during three months prior to the onset of study

3.3.1.5 Abstinence from topical retinoids during three months or oral retinoids during six months prior to the onset of study

3.3.1.6 Abstinence from medications like vitamin C that could stimulate the collagen synthesis.

3.3.1.7 No history of hypertrophic scars or keloids on the abdomen

3.3.1.8 Non smokers

3.3.1.9 The study was approved by the local ethics committee, and all participants gave written informed consent.

3.3.2 Exclusion criteria

3.3.2.1 Participants with defect in the synthesis of collagen such as Ehlers-Danlos syndrome

3.3.2.2 Participants with endocrine disorders such as Cushing's syndrome

3.3.2.3 Participants with abnormal pregnancy such as Polyhydramnios

3.3.2.4 Participants with a history of herpes infections

3.3.2.5 Immunocompromised participants

3.3.3 Discontinuation criteria

3.3.3.1 Participants who had complications from the intervention.

3.3.3.2 Participants who wanted to leave the trial.

3.3.3.3 Participants who did not continue with the intervention (poor compliance).

3.3.3.4 Participants who prevented striae with other therapy beyond the research provided during the trial.

3.4 Tools and Materials

3.4.1 Registration form

3.4.2 Research procedure line

3.4.3 Informed consent

3.4.4 Sunflower oil (Cold pressed 100% Sunflower oil)

Lipids

Saturated fatty acids	10%
Unsaturated fatty acids	87%
Vitamin E	46.70 mg/100g

Thai FDA license number: 10-1-00337-1-0078

3.4.5 Placebo (Mineral oil)

Lipids

Saturated fatty acids	100%
Unsaturated fatty acids	0%
Vitamin E	0 mg/100g

Thai FDA license number: 10-1-5209415

3.4.6 Clear plastic

3.4.7 Digital camera CANON SLR G12 (Canon Inc., Tokyo, Japan)

3.4.8 Digital vernier Mitutoyo series 500 (Midwest FlexSystems, Inc., Japan)

3.4.9 A record of research results

3.4.10 A record of participant satisfaction

3.4.11 A record of side effects

3.5 Procedure

3.5.1 Participants were selected according to the above requirements.

3.5.2 The researcher informed the objectives, procedure, benefits and side effects to the participants in detail.

3.5.3 Participants completed profiles and signed informed consent.

3.5.4 Participants completed general profiles.

3.5.5 Computer assisted randomization was used to allocate participants to the groups. This information was kept confidential from participants and the evaluating physicians.

The randomization methods by random allocation software (Figure 3.2 to 3.5)

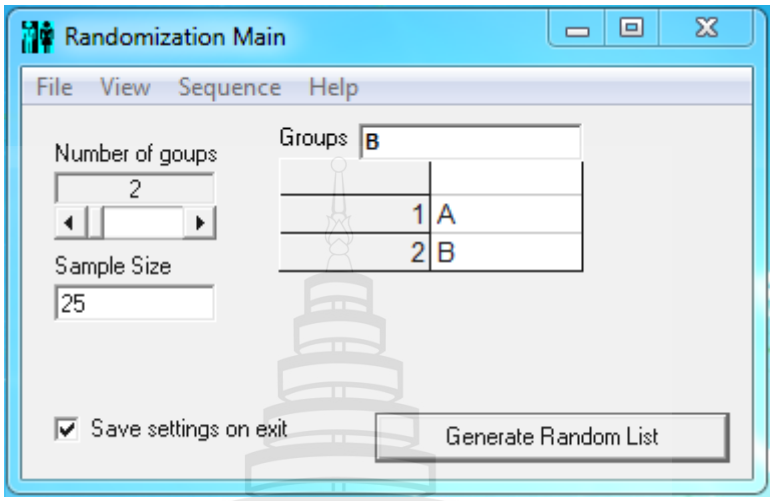


Figure 3.2 Randomization Method 1

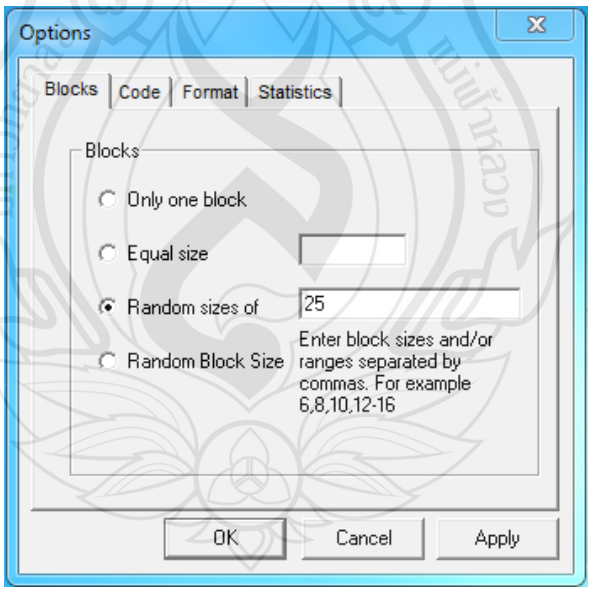


Figure 3.3 Randomization Method 2

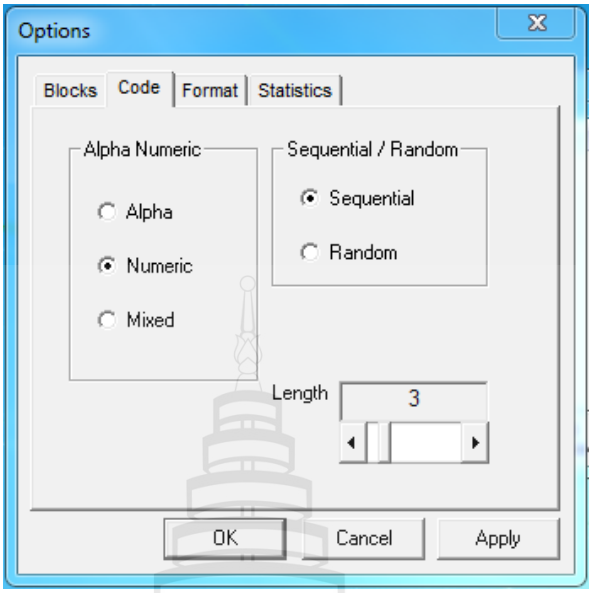


Figure 3.4 Randomization Method 3

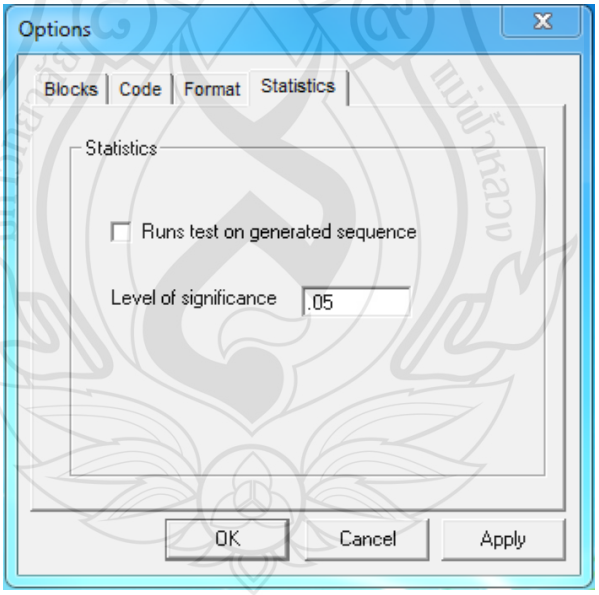


Figure 3.5 Randomization Method 4

001: **B**	006: **B**	011: **A**	016: **B**	021: **A**
002: **B**	007: **A**	012: **A**	017: **A**	022: **B**
003: **B**	008: **B**	013: **A**	018: **A**	023: **B**
004: **A**	009: **A**	014: **A**	019: **B**	024: **B**
005: **A**	010: **A**	015: **B**	020: **A**	025: **B**

Note. Group A = (Right, Left)
Group B = (Left, Right)

Figure 3.6 Group A and Group B were Randomly Selected Using the Computer System.

The abdomen of participants was treated bilaterally (Table 3.1).

Table 3.1 The Treatment of Both Sides of the Abdomen of Group A and Group B

	Sunflower oil	**Placebo**
Group A	Right	Left
Group B	Left	Right

3.5.6 The sunflower oil and the placebo were applied randomly on each side of the abdomen. Participants were instructed to apply the sunflower oil and the placebo without massaging within three minutes after taking a bath twice daily until the time of delivery. Participants were also instructed to use the right hand for the right aspect of abdomen and the left hand for the left aspect of abdomen, during application of the oil.

3.5.7 Taking three photographs of the abdomen with a digital camera: front, left tilted 45º and right tilted 45º from the front view at baseline and every two weeks until delivery.

3.5.8 Digital photographs of intervention sites at each participant visit were obtained by using a digital camera with identical camera settings, lighting and participant positioning. Standardized view with a fixed distance at 50 centimeters was used.

3.5.9 Participants were in supine position for abdominal examination of striae.

3.5.10 Placing a clear plastic on the abdomen and marking the reference points (umbilicus, costal margins, anterior superior iliac spines).

3.5.11 Drawing the lesions (striae) on a clear plastic. The severity of striae gravidarum was evaluated using modified Atwal.

3.5.12 The marking point of striae for width measurement was defined on each side of the abdomen.

3.5.13 A digital vernier was used to measure the width of striae.

3.5.14 Measuring the width of striae with the same marking point (each side) three times to get the average every two weeks until delivery.

3.5.15 Participant satisfaction was evaluated at week 10 and at delivery.

3.5.16 The pruritus score and side effects were evaluated every two weeks until delivery.

3.5.17 Evaluation and analysis of the data by statistical methods

3.5.18 Discussion and conclusion

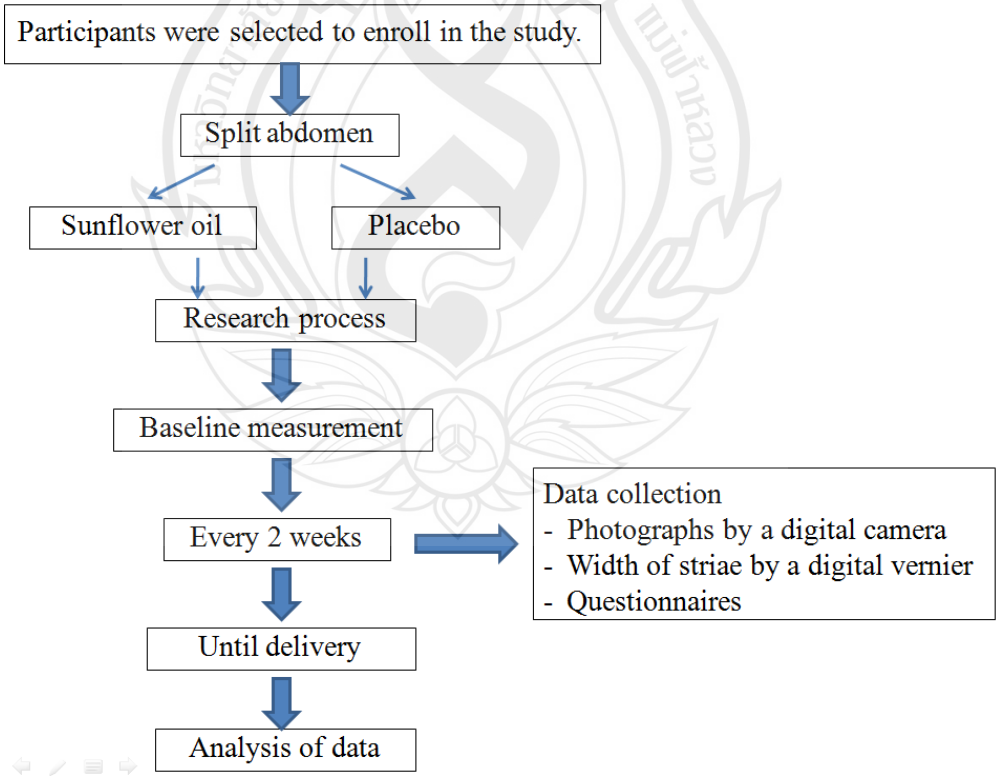


Figure 3.7 Diagram Demonstrating Research Procedure

3.6 Data Collection

3.6.1 The severity of striae gravidarum was evaluated using modified Atwal every two weeks until delivery.

3.6.2 The width of striae was measured with a digital vernier every two weeks until delivery.

3.6.3 Three physicians, who were not part of this study, evaluated the photographs before intervention and after intervention using the global photographic score.

3.6.4 Participant satisfaction was evaluated using visual analog scale at week 10 and at delivery.

3.6.5 The pruritus score was evaluated using visual analog scale every two weeks until delivery.

3.6.6 Evaluation of side effects was carried out using open-ended questions every two weeks until delivery.

3.7 Data Analysis

Data was analyzed using statistical methods.

3.7.1 Qualitative data

3.7.1.1 Incidence of striae gravidarum was summarized using descriptive statistics in the form of frequency and percentage.

3.7.1.2 The incidence of striae gravidarum between sunflower oil and placebo was compared using McNemar test.

3.7.1.3 Severity of striae gravidarum was divided into four classes: no significant striae, mild striae, moderate striae and severe striae; this was summarized using descriptive statistics in the form of frequency and percentage.

3.7.1.4 The severity of striae gravidarum between sunflower oil and placebo was compared using Pearson's chi-square test.

3.7.1.5 The global photographic score between sunflower oil and placebo was compared using Pearson's chi-square test.

3.7.1.6 Side effects were summarized using descriptive statistics in the form of frequency and percentage.

3.7.2 Quantitative data

3.7.2.1 Age, gestational age, body weight, height, body mass index, onset of striae gravidarum were summarized using descriptive statistics in the form of minimum, maximum, mean and standard deviation.

3.7.2.2 The width of striae between sunflower oil and placebo was compared using paired *t*-test in case the data had a normal distribution and the Wilcoxon signed-rank test in case of a non-normal distribution.

3.7.2.3 The participant satisfaction between sunflower oil and placebo was compared using paired *t*-test in case the data had a normal distribution and the Wilcoxon signed-rank test in case of a non-normal distribution.

3.7.2.4 The pruritus score between sunflower oil and placebo was compared using paired *t*-test in case the data had a normal distribution and the Wilcoxon signed-rank test in case of a non-normal distribution.

CHAPTER 4

RESULTS

The main goal of the research was to study the efficacy of sunflower oil in the prevention of striae gravidarum.

Data analysis can be divided into three parts.

1. General characteristics of the sample
2. Analysis of data
3. The satisfaction and side effects

4.1 General Characteristics of the Sample

4.1.1 Demographic information

Thirty-two nulliparous women between the ages of 18 and 40 years with gestational ages between 16 and 18 weeks, who attended Pranangklao hospital for prenatal care. Participants participated in the research in order to prevent striae gravidarum and were followed up every two weeks until delivery. Four participants dropped out due to personal reasons before the end of the study. Overall, 28 participants completed the research.

Table 4.1 General Characteristics of the Participants

	N	%	Mean	SD	Min	Max
Age (years)	32	100.0	22.44	± 4.18	18	33
Gestational age (weeks)	32	100.0	17.51	± 1.02	16.00	18.86
Body weight (kg)	32	100.0	53.94	± 7.65	39	73
Height (cm)	32	100.0	156.84	± 5.79	143	172

Table 4.1 (continued)

	N	%	Mean	SD	Min	Max
BMI (kg/m^2)	32	100.0	21.85	± 2.22	18.52	25.00
Level of education						
Diploma	2	6.3				
Under diploma	30	93.8				
Number of abortion						
0	28	87.5				
1	4	12.5				
Family history of striae gravidarum						
Yes	24	75.0				
No	8	25.0				
Fitzpatrick skin type						
III	7	21.9				
IV	15	46.9				
V	8	25.0				
VI	2	6.3				

Note. BMI, body mass index; SD, standard deviation.

Table 4.1 demonstrates the general characteristics of the participants. The mean age was 22.44 ± 4.18 years (range 18-33). The mean gestational age was 17.51 ± 1.02 weeks (range 16.00-18.86). The mean body weight was 53.94 ± 7.65 kilograms (range 39-73). The mean height was 156.84 ± 5.79 centimeters (range 143-172). The mean BMI was 21.85 ± 2.22 kg/m^2 (range 18.52-25.00). The level of education of most participants was under diploma (93.8%). Most of the participants in both groups were experiencing their first pregnancy (87.5%), while 12.5% had a history of previous abortion. Seventy-five percent of participants had a family history of striae gravidarum in their first degree relatives, while 25.0% had no family history of striae

gravidarum. Most of the participants had Fitzpatrick skin type IV (46.9%). None of the participants had a history of previous scars or keloids on the abdomen.

Table 4.2 The Distribution of Location

Distribution of location	**N**	**%**
Bangkok	3	9.4
Buriram	1	3.1
Burma	6	18.8
Lao	3	9.4
Mukdahan	1	3.1
Nakhonphanom	1	3.1
Nakhonratchasima	2	6.3
Nan	1	3.1
Nongbualamphu	1	3.1
Nongkhai	1	3.1
Nonthaburi	7	21.9
Samutprakan	1	3.1
Sisaket	3	9.4
Surin	1	3.1

Table 4.2 demonstrates the distribution of location among the participants. Most participants lived in Nonthaburi (21.9%). The second location in which most participants lived was Burma (18.8%). The third locations were Bangkok, Lao and Sisaket (9.4%).

4.2 Analysis of Data

Table 4.3 The Occurrence of Striae Gravidarum

Group	Striae	%	No striae	%	Total	*p*-value
Sunflower oil	15	53.6	13	46.4	**28**	0.711
Placebo	16	57.1	12	42.9	**28**	
Total	**31**	**55.4**	**25**	**44.6**	**56**	

Note. *p*-value from McNemar test

Table 4.3 and Figure 4.1 demonstrate the occurrence of striae gravidarum. Overall, the incidence of striae gravidarum was 55.4%. In the sunflower oil group, the incidence of striae gravidarum was 53.6%. On the other hand, the incidence of striae gravidarum in the placebo group was 57.1%. McNemar test indicated no statistically significant difference between the two groups (p = 0.711). No significant prevention of striae gravidarum was achieved by application of the selected oil.

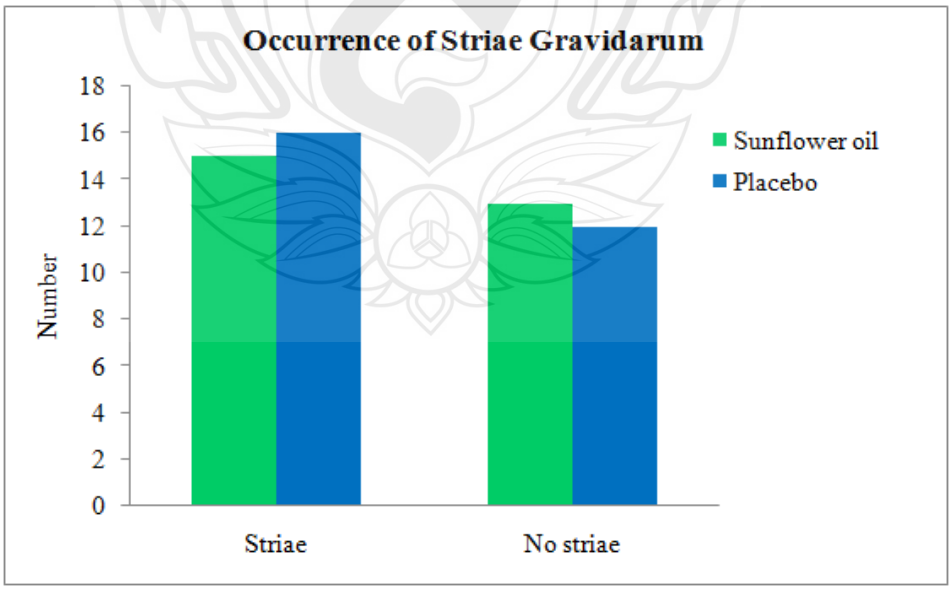


Figure 4.1 The Occurrence of Striae Gravidarum

Table 4.4 The Onset of Striae Gravidarum

	n	%	Mean	SD	Min	Max
Gestational age (weeks)	16	57.1	31.46	± 5.02	19.29	39.00

Table 4.4 demonstrates the onset of striae gravidarum. Out of 28 participants, only 16 participants developed striae gravidarum. The mean gestational age at which striae gravidarum first appeared was 31.46 ± 5.02 weeks. The minimum gestational age at onset of striae gravidarum was 19.29 weeks. The maximum gestational age at onset of striae gravidarum was 39 weeks. The mean age of participants with striae gravidarum was 21.38 ± 2.78 years. On the other hand, the mean age of participants without striae gravidarum was 22.33 ± 4.29 years.

Table 4.5 The Severity of Striae Gravidarum

Group	No significant striae		Mild striae		Moderate striae		Severe striae		Total
	n	%	n	%	n	%	n	%	
Sunflower oil	4	25.0	4	25.0	5	31.3	3	18.8	**16**
Placebo	2	12.5	5	31.3	5	31.3	4	25.0	**16**
Total	**6**	**18.8**	**9**	**28.1**	**10**	**31.3**	**7**	**21.9**	**32**

Table 4.5 and Figure 4.2 demonstrate the severity of striae gravidarum. Among 28 participants, only 16 participants developed striae gravidarum. The severity of striae gravidarum was divided into four classes: no significant striae, mild striae, moderate striae and severe striae. The incidence of no significant striae in the sunflower oil group was 25.0%, while in the placebo group was 12.5%. The incidence of mild striae in sunflower oil group and placebo group was 25.0% and 31.3% respectively. While the incidence of moderate striae in both sunflower oil and placebo groups was equal being 31.3%. Lastly, the incidence of severe striae in sunflower oil group and placebo group was 18.8% and 25.0% respectively.

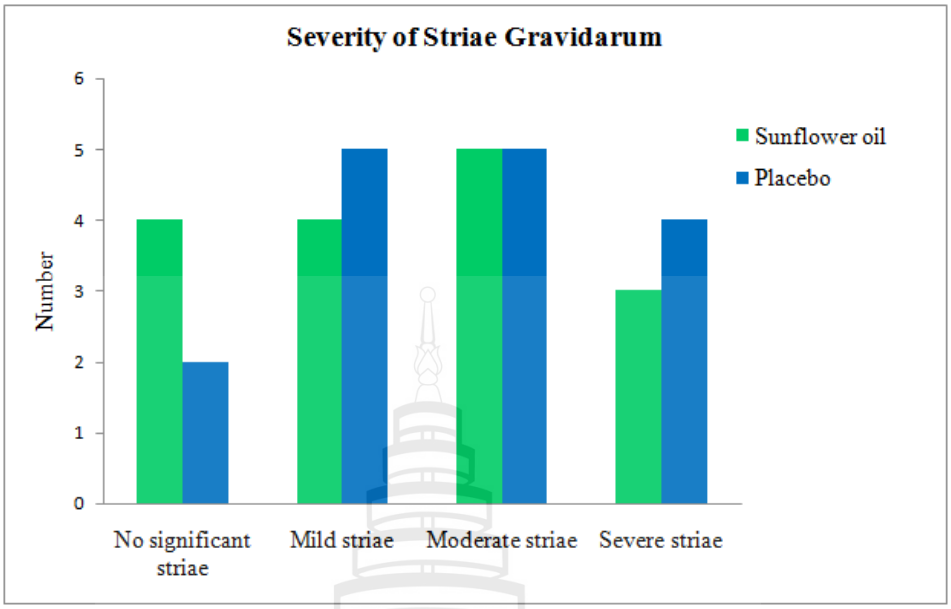


Figure 4.2 The Severity of Striae Gravidarum

Table 4.6 The Width of Striae Gravidarum at Delivery between Sunflower Oil Group and Placebo Group

Case	Delivery							
	Sunflower oil				Placebo			
	Measure 1 (mm)	Measure 2 (mm)	Measure 3 (mm)	Mean (mm)	Measure 1 (mm)	Measure 2 (mm)	Measure 3 (mm)	Mean (mm)
2	2.01	2.08	2.04	2.04	2.09	2.06	2.07	2.07
4	0.00	0.00	0.00	0.00	3.64	3.53	3.80	3.66
7	2.98	3.05	2.94	2.99	3.89	3.82	3.97	3.89
8	4.19	4.22	4.15	4.19	3.49	3.57	3.55	3.54
10	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
12	3.13	3.08	3.21	3.14	3.41	3.61	3.36	3.46
15	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
16	1.58	1.63	1.78	1.66	1.90	1.97	1.81	1.89
19	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
21	5.19	5.23	5.14	5.19	6.13	5.95	6.02	6.03
22	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Table 4.6 (continued)

Case	Delivery							
	Sunflower oil				Placebo			
	Measure 1 (mm)	Measure 2 (mm)	Measure 3 (mm)	Mean (mm)	Measure 1 (mm)	Measure 2 (mm)	Measure 3 (mm)	Mean (mm)
25	3.15	3.09	3.10	3.11	3.17	3.11	3.06	3.11
26	2.35	2.23	2.28	2.29	2.38	2.36	2.41	2.38
28	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
29	3.92	3.88	4.01	3.94	4.21	4.28	4.17	4.22
32	3.45	3.34	3.28	3.36	3.61	3.57	3.73	3.64

Table 4.6 demonstrates the width of striae gravidarum at delivery between sunflower oil group and placebo group. Among 28 participants, only 16 participants developed striae gravidarum. Out of 16 participants, five participants dropped out for personal reasons. Overall, there were 11 participants who were capable of measuring the width of striae. The striae of each participant were measured from the same reference points. This was done three times using a digital vernier.

Table 4.7 Comparison of the Mean Width at Delivery between Sunflower Oil Group and Placebo Group

Case	Mean width at delivery (mm)		*p*-value
	Sunflower oil	Placebo	
2	2.04	2.07	
4	0.00	3.66	
7	2.99	3.89	
8	4.19	3.54	
10	N/A	N/A	
12	3.14	3.46	
15	N/A	N/A	
16	1.66	1.89	
19	N/A	N/A	
21	5.19	6.03	

Table 4.7 (continued)

Case	Mean width at delivery (mm)		*p*-value
	Sunflower oil	Placebo	
22	N/A	N/A	
25	3.11	3.11	
26	2.29	2.38	
28	N/A	N/A	
29	3.94	4.22	
32	3.36	3.64	
Mean ± SD	2.90 ± 1.40	3.44 ± 1.15	0.137

Table 4.7 demonstrates the mean width of striae at delivery between sunflower oil group and placebo group. The mean width at delivery in the sunflower oil group was 2.90 ± 1.40 mm. The mean width at delivery in the placebo group was 3.44 ± 1.15 mm. There was no statistically significant difference in the mean width at delivery between both groups ($p = 0.137$) (Figure 4.3).

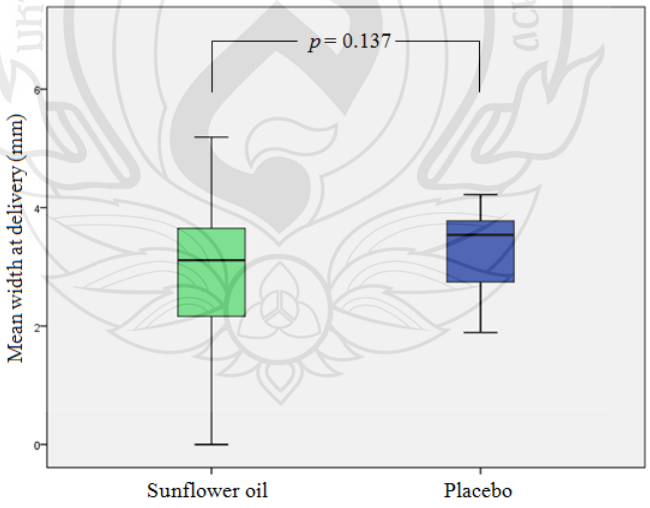


Figure 4.3 Comparison of the Mean Width at Delivery between Sunflower Oil Group and Placebo Group

Table 4.8 The Global Photographic Score

Case	Sunflower oil			Placebo		
	Physician 1	**Physician 2**	**Physician 3**	**Physician 1**	**Physician 2**	**Physician 3**
1	N/A	N/A	N/A	N/A	N/A	N/A
2	0	0	0	1	1	1
3	N/A	N/A	N/A	N/A	N/A	N/A
4	0	0	0	2	1	1
5	0	0	0	0	0	0
6	0	0	0	0	0	0
7	1	1	1	2	1	1
8	3	3	3	3	3	3
9	0	0	0	0	0	0
10	3	3	3	3	3	3
11	0	0	0	0	0	0
12	1	2	2	2	2	2
13	0	0	0	0	0	0
14	0	0	0	0	0	0
15	1	1	1	1	1	1
16	0	0	0	1	0	0
17	0	0	0	0	0	0
18	0	0	0	0	0	0
19	2	2	2	2	2	2
20	N/A	N/A	N/A	N/A	N/A	N/A
21	3	3	3	3	3	3
22	2	2	2	2	2	2
23	0	0	0	0	0	0
24	0	0	0	0	0	0
25	0	0	0	0	0	0
26	1	1	1	2	1	1
27	0	0	0	0	0	0
28	2	2	2	2	2	2
29	3	3	3	3	3	3
30	0	0	0	0	0	0
31	N/A	N/A	N/A	N/A	N/A	N/A
32	2	2	2	1	1	1

Note. -3 = Greatly decreased
-2 = Moderately decreased
-1 = Slightly decreased
0 = No change
1 = Slightly increased
2 = Moderately increased
3 = Greatly increased

Table 4.8 demonstrates the global photographic score which was evaluated by three physicians before intervention and after intervention. Among 32 participants, only 28 participants were enrolled. This table shows the global photographic score of 28 participants in both sunflower oil and placebo groups.

Table 4.9 The Frequency of Global Photographic Score

Group	No change		Slightly increased		Moderately increased		Greatly increased		Total	*p*-value
	n	%	n	%	n	%	n	%		
Sunflower oil	48	57.1	10	11.9	14	16.7	12	14.3	**84**	0.579
Placebo	41	48.8	16	19.0	15	17.9	12	14.3	**84**	
Total	**89**	**53.0**	**26**	**15.5**	**29**	**17.3**	**24**	**14.3**	**168**	

Note. *p*-value from Pearson's chi-square test

Table 4.9 and Figure 4.4 demonstrate the frequency of global photographic score. The global photographic score was divided into seven groups. In our study, the appearance of striae did not improve in all the participants. Therefore there were only four groups: no change, slightly increased, moderately increased and greatly increased. No change of striae occurred in sunflower oil group and placebo group was 57.1% and 48.8% respectively. However, striae were slightly increased in the sunflower oil group with 11.9% and 19.0% in the placebo group. Striae were moderately increased in the sunflower oil group with 16.7% and 17.9% in the placebo

group. Striae were greatly increased in both groups with 14.3% equally. However, there was no statistically significant difference in the global photographic score between sunflower oil group and placebo group ($p = 0.579$).

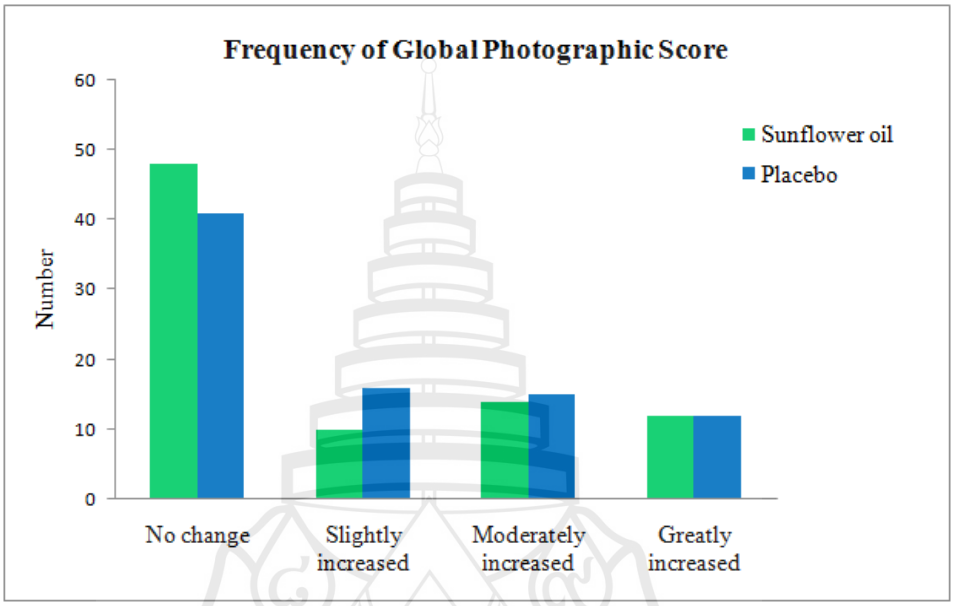


Figure 4.4 The Frequency of Global Photographic Score

4.3 The Satisfaction and Side Effects

Participant satisfaction was evaluated at week 10 and at delivery using visual analog scale ranging from 0% to 100%.

0%-20% = Slight improvement
20%-40% = Mild improvement
40%-60% = Moderate improvement
60%-80% = Good improvement
80%-100% = Very good improvement

Table 4.10 Participant Satisfaction at Week 10 between Sunflower Oil Group and Placebo Group

Case	Satisfaction at week 10 (%)		*p*-value
	Sunflower oil	Placebo	
1	N/A	N/A	
2	40.0	60.0	
3	N/A	N/A	
4	60.0	80.0	
5	80.0	60.0	
6	10.0	60.0	
7	100.0	70.0	
8	100.0	10.0	
9	90.0	70.0	
10	70.0	50.0	
11	80.0	50.0	
12	100.0	100.0	
13	50.0	90.0	
14	50.0	40.0	
15	100.0	70.0	
16	80.0	50.0	
17	80.0	90.0	
18	60.0	60.0	
19	70.0	70.0	
20	N/A	N/A	
21	70.0	50.0	
22	80.0	80.0	
23	50.0	70.0	
24	70.0	60.0	
25	40.0	100.0	
26	90.0	90.0	

Table 4.10 (continued)

Case	Satisfaction at week 10 (%)		*p*-value
	Sunflower oil	Placebo	
27	50.0	50.0	
28	100.0	100.0	
29	30.0	40.0	
30	80.0	80.0	
31	N/A	N/A	
32	70.0	90.0	
Mean ± SD	69.64 ± 23.33	67.50 ± 21.37	0.700

Table 4.10 demonstrates the participant satisfaction at week 10 between sunflower oil group and placebo group. Among 32 participants, only 28 participants were enrolled. The mean satisfaction at week 10 in the sunflower oil group was 69.64 ± 23.33. The mean satisfaction at week 10 in the placebo group was 67.50 ± 21.37. There was no statistically significant difference between sunflower oil group and placebo group ($p = 0.700$) (Figure 4.5).

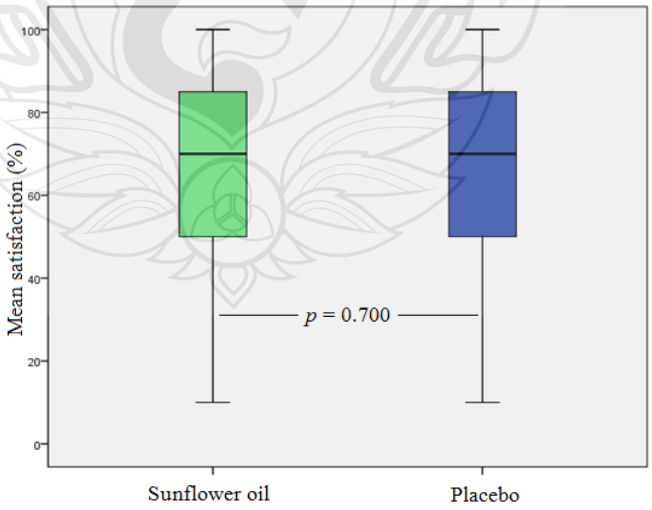


Figure 4.5 Comparison of the Mean Satisfaction at Week 10 between Sunflower Oil Group and Placebo Group

Table 4.11 Participant Satisfaction at Delivery between Sunflower Oil Group and Placebo Group

Case	Satisfaction at delivery (%)		*p*-value
	Sunflower oil	Placebo	
1	N/A	N/A	
2	60.0	40.0	
3	N/A	N/A	
4	80.0	80.0	
5	100.0	100.0	
6	90.0	90.0	
7	90.0	80.0	
8	60.0	40.0	
9	80.0	60.0	
10	70.0	50.0	
11	90.0	60.0	
12	40.0	40.0	
13	70.0	90.0	
14	70.0	50.0	
15	100.0	80.0	
16	80.0	60.0	
17	80.0	80.0	
18	60.0	60.0	
19	70.0	50.0	
20	N/A	N/A	
21	40.0	30.0	
22	80.0	80.0	
23	90.0	100.0	
24	80.0	70.0	
25	70.0	100.0	
26	90.0	90.0	

Table 4.11 (continued)

Case	Satisfaction at delivery (%)		*p*-value
	Sunflower oil	Placebo	
27	50.0	50.0	
28	30.0	80.0	
29	40.0	50.0	
30	90.0	90.0	
31	N/A	N/A	
32	70.0	80.0	
Mean ± SD	72.14 ± 18.93	68.93 ± 20.79	0.190

Note. *p*-value from Wilcoxon signed-rank test

Table 4.11 demonstrates the participant satisfaction at delivery between sunflower oil group and placebo group. The mean satisfaction at delivery in the sunflower oil group was 72.14 ± 18.93. The mean satisfaction at delivery in the placebo group was 68.93 ± 20.79. Wilcoxon signed-rank test was used due to the data was not normally distributed. There was no statistically significant difference between sunflower oil group and placebo group ($p = 0.190$) (Figure 4.6).

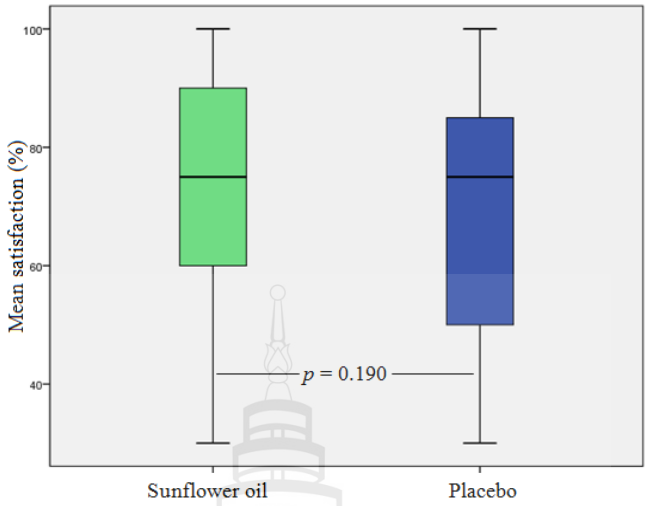


Figure 4.6 Comparison of the Mean Satisfaction at Delivery between Sunflower Oil Group and Placebo Group

Table 4.12 Comparison of the Mean Pruritus Score between Sunflower Oil Group and Placebo Group

	Group	**Pruritus score**				***p*-value**
	N = 28	**Mean**	**SD**	**Min**	**Max**	
Week 2	Sunflower oil	0.61	± 1.26	0	5	0.593
	Placebo	0.46	± 0.92	0	3	
Week 4	Sunflower oil	1.39	± 1.66	0	5	0.794
	Placebo	1.39	± 1.66	0	5	
Week 6	Sunflower oil	1.36	± 1.97	0	7	0.305
	Placebo	1.57	± 1.99	0	7	
Week 8	Sunflower oil	1.07	± 1.88	0	8	0.577
	Placebo	1.21	± 2.17	0	10	
Week 10	Sunflower oil	1.14	± 1.69	0	6	0.068
	Placebo	1.68	± 1.98	0	6	
Week 12	Sunflower oil	1.46	± 1.90	0	7	0.527
	Placebo	1.39	± 1.95	0	7	
Week 14	Sunflower oil	1.29	± 1.86	0	7	0.589
	Placebo	1.21	± 1.89	0	7	

Table 4.12 (continued)

	Group	Pruritus score				*p*-value
	N = 28	Mean	SD	Min	Max	
Week 16	Sunflower oil	0.96	± 1.69	0	7	0.157
	Placebo	1.04	± 1.71	0	7	
Week 18	Sunflower oil	1.14	± 1.88	0	8	1.000
	Placebo	1.11	± 1.87	0	8	
Week 20	Sunflower oil	1.32	± 2.47	0	10	0.655
	Placebo	1.29	± 2.48	0	10	
Week 22	Sunflower oil	1.57	± 2.25	0	8	0.180
	Placebo	1.68	± 2.33	0	8	

Table 4.12 demonstrates the mean pruritus score between sunflower oil group and placebo group which was evaluated by participants every two weeks until delivery. The maximum mean pruritus score in the sunflower oil group was 1.57 ± 2.25. The maximum mean pruritus score in the placebo group was 1.68 ± 2.33. There was no statistically significant difference between sunflower oil group and placebo group in each two weeks.

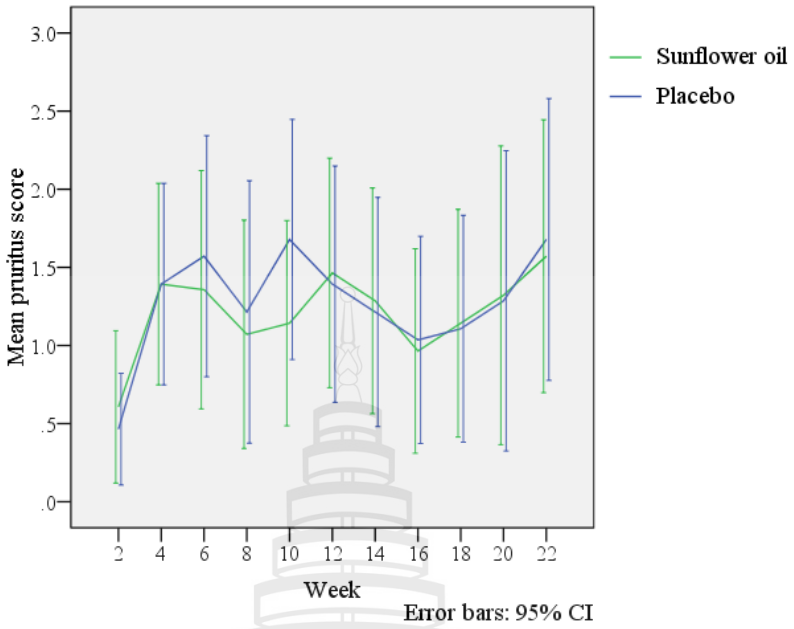


Figure 4.7 Comparison of the Mean Pruritus Score between Sunflower Oil Group and Placebo Group

Figure 4.7 illustrates the mean pruritus score every two weeks from week 2 until delivery of both sunflower oil and placebo groups. The highest difference in the mean pruritus score between sunflower oil group and placebo group was observed at week 10. However, there was no statistically significant difference between the two groups in each two weeks.

Table 4.13 The Side Effects

	Side effects				
Group	**Rash**	**%**	**Folliculitis**	**%**	**Total**
Sunflower oil	2	50.0	2	50.0	**4**
Placebo	3	60.0	2	40.0	**5**
Total	**5**	**55.6**	**4**	**44.4**	**9**

Table 4.13 and Figure 4.8 demonstrate the side effects which were evaluated by a researcher. Overall, there were nine participants with side effects. The side effects were rash and folliculitis. Rash occurred in five participants, while folliculitis occurred in four participants. There were two participants who developed rash in the sunflower oil group, while there were three participants who developed rash in the placebo group. On the other hand, there were two participants with folliculitis in each group. No participants had both rash and folliculitis.

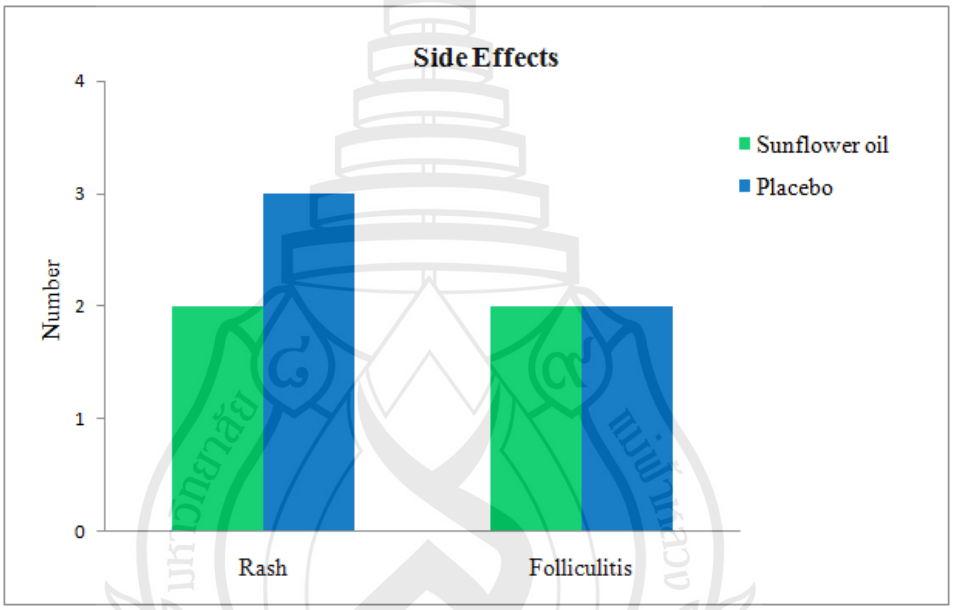


Figure 4.8 The Side Effects

CHAPTER 5

DISCUSSION AND CONCLUSION

5.1 Discussion of General Information

The study included 32 nulliparous women between the ages of 18 and 40 years with gestational ages between 16 and 18 weeks. Participants were followed up every two weeks until delivery. Four participants dropped out of the research before the end of the study. Overall, there were 28 participants who completed the research.

5.1.1 Age

The mean age was 22.44 ± 4.18 years (range 18-33). The mean age of participants with striae gravidarum was 21.38 ± 2.78 years. On the other hand, the mean age of participants without striae gravidarum was 22.33 ± 4.29 years. Striae gravidarum are more common in younger primigravidas than in older pregnant women (Bolognia et al., 2007).

5.1.2 Gestational age

The mean gestational age was 17.51 ± 1.02 weeks (range 16.00-18.86). According to the study of Poidevin, striae gravidarum did not develop during the gestational ages between 16 and 18 weeks (Poidevin, 1959).

5.1.3 Body weight, height and BMI

The mean body weight was 53.94 ± 7.65 kilograms (range 39-73). The mean height was 156.84 ± 5.79 centimeters (range 143-172). The mean BMI was 21.85 ± 2.22 kg/m^2 (range 18.52-25.00). According to the study of Ghasemi, a mean BMI of 22.20 ± 4.37 kg/m^2 was not associated with the occurrence of striae gravidarum (Ghasemi et al., 2007). In our study, the mean BMI was less than 22.20 ± 4.37 kg/m^2.

5.1.4 Education

The level of education of most participants was under diploma (93.8%).

5.1.5 History of previous abortion

Most of the participants in both groups were experiencing their first pregnancy (87.5%), while 12.5% had a history of previous abortion.

5.1.6 Family history of striae gravidarum

Seventy-five percent of participants had a family history of striae gravidarum in their first degree relatives, while 25.0% had no family history of striae gravidarum. A positive family history of striae gravidarum is associated with the occurrence of striae gravidarum (J-Orh et al., 2008).

5.1.7 Fitzpatrick skin type

In our study, all participants were Asians and predominantly Thais. Most of the participants had Fitzpatrick skin type IV (46.9%). However, striae gravidarum are more common among Caucasians (Bolognia et al., 2007).

5.2 Discussion of Experimental Results and Previous Research

5.2.1 The occurrence of striae gravidarum

Overall, the incidence of striae gravidarum in our study was 55.4%. As discussed in the literature review, the incidence of striae development during pregnancy is approximately 75% (Bolognia et al., 2007). Rates of occurrence of striae gravidarum vary ranging between 50% and 90% (Osman et al., 2007). The incidences in primiparous women are reported to be 52% (Atwal et al., 2006), 61% (Osman et al., 2007) and 87.7% (Ghasemi et al., 2007) in different studies. In Thailand, the prevalence of striae gravidarum is 77% (J-Orh et al., 2008).

5.2.2 Striae gravidarum prevention

Overall, the incidence of striae gravidarum was 55.4%. In the sunflower oil group, the incidence of striae gravidarum was 53.6%. On the other hand, the incidence of striae gravidarum in the placebo group was 57.1%. There was no statistically significant difference between the two groups ($p = 0.711$). There was no significant benefit regarding prevention of striae gravidarum. Various vegetable oils such as olive oil, almond oil and cocoa butter are used traditionally to prevent striae gravidarum. According to a previous study conducted on olive oil, 45.7% of the olive oil users and 62.9% of the controls developed striae gravidarum (Taavoni et al., 2011). A subsequent study by Soltanipoor demonstrated that the incidence of striae gravidarum was 36% in the olive oil group and 40% in the control group (Soltanipoor et al., 2012). Another study about the cocoa butter lotion showed that the incidence of striae gravidarum in cocoa butter group and placebo group was 44% and 55% respectively (Buchanan et al., 2010). Table 5.1 demonstrates the efficacy of herbal therapy in the prevention of striae gravidarum (presented as number needed to treat).

Table 5.1 The Efficacy of Herbal Therapy in the Prevention of Striae Gravidarum

Herbal therapy	Treatment of choices	Efficacy
Olive oil	Prevention of SG	NNT = 5.81
Almond oil	Prevention of SG	NNT = 4.72
Cocoa butter lotion	Prevention of SG	NNT = 9.09

Note. SG, striae gravidarum; NNT, number needed to treat.

Source Buchanan et al. (2010); Taavoni et al. (2011); Timur Tashan and Kafkasli (2012)

A meta-analysis review regarding topical preparations for preventing striae gravidarum demonstrated no significant benefit (Brennan et al., 2012). In our study, the result was similar to the previous studies. There was no significance in the prevention of striae gravidarum.

We considered modulation of collagen synthesis by vitamin E to be the major mechanism in the prevention of striae gravidarum. However, our result of prevention showed no difference from the placebo. Since the exact causes of striae remain unknown. Other mechanisms may play a role for the striae development such as the stretch theory, hormone theory and connective tissue related stretching theory.

5.2.3 The onset of striae gravidarum

In our study, the mean gestational age at which striae gravidarum first appeared was 31.46 ± 5.02 weeks. The minimum gestational age at onset of striae gravidarum was 19.29 weeks. The maximum gestational age at onset of striae gravidarum was 39 weeks. In the light of previous studies, striae gravidarum are common during the first pregnancy (Salter & Kimball, 2006). They usually present during the third trimester (Atwal et al., 2006; Cunningham et al., 2009). According to the study of Ghasemi, the mean gestational age at which striae gravidarum first appeared was 27.57 ± 5.38 weeks (Ghasemi et al., 2007). However, Chang reported that striae gravidarum may appear in women under 24 weeks of gestational age (Chang et al., 2004).

5.2.4 The severity of striae gravidarum

Among 28 participants, only 16 participants developed striae gravidarum. The severity of striae gravidarum was divided into four classes: no significant striae, mild striae, moderate striae and severe striae. The incidence of no significant striae in the sunflower oil group was 25.0%, while in the placebo group was 12.5%. The incidence of mild striae in sunflower oil group and placebo group was 25.0% and 31.3% respectively. While the incidence of moderate striae in both sunflower oil and placebo groups was equal being 31.3%. Lastly, the incidence of severe striae in sunflower oil group and placebo group was 18.8% and 25.0% respectively. According to a previous study, the olive oil reduced the incidence of severe striae gravidarum. However, the use of olive oil did not significantly reduce the incidence and severity of striae gravidarum (Soltanipoor et al., 2012). In our study, the sunflower oil reduced the incidence of severe striae gravidarum which was similar to the study of olive oil. Furthermore, the sunflower oil also reduced the incidence of mild striae gravidarum. However, our data analysis had limitation due to limited sample size; therefore the data could not be analyzed by statistics. The results might have been similar to Brennan, if the sample size of our study

was adequate. A meta-analysis review demonstrated no benefit in terms of reducing the severity of striae gravidarum (Brennan et al., 2012).

5.2.5 The width of striae gravidarum

The width of striae was measured every two weeks until delivery once the striae gravidarum developed. The mean width at delivery in sunflower oil group and placebo group was 2.90 ± 1.40 mm and 3.44 ± 1.15 mm respectively. However, there was no statistically significant difference in the mean width at delivery between both groups (p = 0.137). No previous study has addressed the issue based on the width of these lesions.

5.2.6 The global photographic score

The global photographic score was evaluated by three physicians before intervention and after intervention. The global photographic score was divided into seven groups. In our study, the appearance of striae did not improve in all the participants. Therefore there were only four groups: no change, slightly increased, moderately increased and greatly increased. No change of striae occurred in sunflower oil group and placebo group was 57.1% and 48.8% respectively. However, striae were slightly increased in the sunflower oil group with 11.9% and 19.0% in the placebo group. Striae were moderately increased in the sunflower oil group with 16.7% and 17.9% in the placebo group. Striae were greatly increased in both groups with 14.3% equally. However, there was no statistically significant difference between sunflower oil group and placebo group (p = 0.579). The results demonstrated no difference in the global photographic score between the two groups.

5.2.7 Participant satisfaction

The mean satisfaction at week 10 in the sunflower oil group was 69.64 ± 23.33. The mean satisfaction at week 10 in the placebo group was 67.50 ± 21.37. At week 10, there was no statistically significant difference between sunflower oil group and placebo group (p = 0.700). The mean satisfaction at delivery in the sunflower oil group was 72.14 ± 18.93. The mean satisfaction at delivery in the placebo group was 68.93 ± 20.79. At delivery, there was also no statistically significant difference between sunflower oil group and placebo group (p = 0.190). The mean satisfaction at delivery was higher than the

mean satisfaction at week 10 in both groups. The results showed that the participants preferred to use the sunflower oil more than the placebo.

5.2.8 The pruritus score

The pruritus score was evaluated by participants every two weeks until delivery. The maximum mean pruritus score in the sunflower oil group was 1.57 ± 2.25. The maximum mean pruritus score in the placebo group was 1.68 ± 2.33. The highest difference in the mean pruritus score between sunflower oil group and placebo group was observed at week 10. However, there was no statistically significant difference between the two groups in each two weeks.

5.2.9 The side effects

The side effects were evaluated by a researcher. Overall, there were nine participants with side effects. The side effects were rash and folliculitis. Rash occurred in five participants, while folliculitis occurred in four participants. There were two participants who developed rash in the sunflower oil group, while there were three participants who developed rash in the placebo group. On the other hand, there were two participants with folliculitis in each group. No participants had both rash and folliculitis.

The treatment of rash was to discontinue the application of oil and apply calamine lotion for relieving the pruritus. The symptoms improved within three to five days. It was important to find the cause of the rash whether it was from the oil or other agents. For the folliculitis, it resolved by itself within two to three weeks.

Vitamin E has been assigned to pregnancy category A by the FDA when used in doses that are advocated by the FDA. Doses exceeding the recommended dietary allowance (300 mg/day) have been assigned to pregnancy category C. In our study, the vitamin E content in sunflower oil was 0.0467% by weight, so the side effects rarely occurred (“Material Safety Data Sheet Vitamin E MSDS”, 2013).

5.3 Conclusion

Overall, the incidence of striae gravidarum was 55.4%. The incidence of striae gravidarum was 53.6% in the sunflower oil group and 57.1% in the placebo group. There was no statistical significance in the prevention of striae gravidarum (p = 0.711). The mean gestational age at which striae gravidarum first appeared was 31.46 ± 5.02 weeks (range 19.29-39.00). Although the sunflower oil group resulted in a clinically lower incidence of mild striae and severe striae than the placebo group, the incidence of moderate striae was the same for both groups. There was no statistically significant difference in the mean width at delivery between sunflower oil group and placebo group. For the global photographic score and participant satisfaction, the results demonstrated no statistically significant difference between sunflower oil group and placebo group. The highest difference in the mean pruritus score between sunflower oil group and placebo group was observed at week 10. However, there was no statistically significant difference between the two groups in each two weeks. There were few side effects.

5.4 Suggestions

5.4.1 The researcher should explain the natural disease of striae gravidarum in order to reduce the participant's anxiety.

Striae rubra are usually turned to striae alba. Striae alba are usually permanent, but after some years they may fade.

5.4.2 The researcher should emphasize the importance of compliance because poor compliance leads to undetermined precise results.

5.4.3 Any intervention should be carried out before the histological changes occur. Histological changes occur approximately four weeks before the occurrence of striae (Sheu et al., 1991). In our study, the mean gestational age at which striae gravidarum first appeared was 31.46 ± 5.02 weeks. Therefore the optimal time for the intervention is 27.46 ± 5.02 weeks. However, earlier application of the sunflower oil may significantly reduce the occurrence of striae gravidarum.

5.4.4 There should be a large sample size in the group of participants with the presence of striae gravidarum. In our study, there was inadequate sample size of the participants in the severity group. Therefore the data could not be analyzed by statistics.

5.4.5 Indirect method for evaluating the physical property such as a cutometer may provide the risk factors for the occurrence of striae gravidarum.

5.4.6 High content of vitamin E in sunflower oil may not be enough to prevent striae gravidarum. There should be a further study on the mechanism of striae gravidarum.

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APPENDICES

APPENDIX A

INFORMED CONSENT FORM

หนังสือยินยอมเข้าร่วมโครงการวิจัย (Informed Consent Form)

วันที่.....เดือน.....พ.ศ. .....

ข้าพเจ้า (นาย/นาง/นางสาว)..... อายุ.....ปี อยู่บ้านเลขที่.....
หมู่ที่.....ถนน.....ตำบล.....อำเภอ.....
จังหวัด.....รหัสไปรษณีย์.....

ขอทำหนังสือแสดงความยินยอมเข้าร่วมโครงการวิจัยเพื่อเป็นหลักฐานแสดงว่า

1. ข้าพเจ้ายินยอมเข้าร่วมโครงการวิจัยของ แพทย์หญิงณิชา เจนมานะชัยกุล และผู้ช่วยศาสตราจารย์แพทย์หญิงสุนิสา ไทยจินดา เรื่อง การศึกษาประสิทธิภาพของน้ำมันดอกทานตะวันในการป้องกันภาวะท้องลายจากการตั้งครรภ์ (THE EFFICACY OF SUNFLOWER OIL IN THE PREVENTION OF STRIAE GRAVIDARUM) ด้วยความสมัครใจ โดยมิได้มีการบังคับ หลอกลวงแต่ประการใด และพร้อมจะให้ความร่วมมือในการวิจัย

2. ข้าพเจ้าได้รับการอธิบายและตอบข้อสงสัยจากผู้วิจัยเกี่ยวกับวัตถุประสงค์การวิจัย วิธีการวิจัย ความปลอดภัย อาการ หรืออันตรายที่อาจเกิดขึ้น รวมทั้งประโยชน์ที่จะได้รับจากการวิจัย โดยละเอียดแล้วตามเอกสารชี้แจงผู้เข้าร่วมการวิจัยแนบท้าย

3. ข้าพเจ้าได้รับการรับรองจากผู้วิจัยว่าจะเก็บข้อมูลส่วนตัวของข้าพเจ้าเป็นความลับ จะเปิดเผยได้เฉพาะในรูปแบบของการสรุปผลการวิจัยเท่านั้น

4. ข้าพเจ้าได้รับทราบจากผู้วิจัยแล้วว่า หากเกิดอันตรายใดๆจากการวิจัย ผู้วิจัยจะรับผิดชอบค่ารักษาพยาบาลที่เป็นผลสืบเนื่องจากการวิจัยนี้

5. ข้าพเจ้าได้รับทราบว่า ข้าพเจ้ามีสิทธิที่จะถอนตัวออกจากการวิจัยครั้งนี้เมื่อใดก็ได้ โดยไม่มีผลกระทบใดๆต่อการรักษาพยาบาลตามสิทธิ์ที่ข้าพเจ้าควรได้รับ

ข้าพเจ้าได้อ่านและเข้าใจข้อความตามหนังสือนี้แล้ว จึงได้ลงลายมือชื่อไว้เป็นสำคัญ พร้อมกับหัวหน้าโครงการวิจัยและพยาน

ลงชื่อ..... ผู้ยินยอม/ผู้ปกครอง

(.....)

ลงชื่อ..... หัวหน้าโครงการวิจัย

(แพทย์หญิงณิชา เจนมานะชัยกุล)

ลงชื่อ..... พยาน

(.....)

ลงชื่อ..... พยาน

(.....)

APPENDIX B

INFORMATION SHEET

เอกสารชี้แจงข้อมูลแก่ผู้เข้าร่วมโครงการวิจัย

1. ชื่อโครงการวิจัย

การศึกษาประสิทธิภาพของน้ำมันดอกทานตะวันในการป้องกันภาวะท้องลายจากการตั้งครรภ์

2. วัตถุประสงค์

2.1 เพื่อศึกษาประสิทธิภาพของน้ำมัน 2 ชนิด ว่ามีผลแตกต่างในเรื่องการป้องกันภาวะท้องลายที่เกิดจากการตั้งครรภ์

2.2 เพื่อศึกษาผลข้างเคียงและความพึงพอใจหลังจากได้ใช้น้ำมัน 2 ชนิด

3. ความเป็นมาของโครงการ

รอยแตกลาย เป็นภาวะที่ผิวหนังมีลักษณะแตกออกเป็นริ้วๆ ซึ่งมักจะสัมพันธ์กับการที่มีการยืดตัวของผิวหนังมากขึ้นอย่างต่อเนื่อง สามารถพบร่วมกับการเปลี่ยนแปลงของร่างกาย เช่น ย่างเข้าวัยรุ่น การตั้งครรภ์ การเจริญเติบโตอย่างรวดเร็วในเด็ก น้ำหนักที่เพิ่มขึ้นหรือลดลงอย่างรวดเร็ว และความอ้วน รวมถึงภาวะความผิดปกติของฮอร์โมนคอร์ติซอลที่มากเกิน

ภาวะท้องลายส่วนใหญ่เริ่มเกิดขณะตั้งครรภ์ที่อายุครรภ์ประมาณ 5-8 เดือน อุบัติการณ์การเกิดอยู่ที่ 75%

สาเหตุของรอยแตกลายยังไม่ทราบแน่ชัด แต่ปัจจัยที่มีผลต่อการเกิดภาวะนี้ ได้แก่ ฮอร์โมน การขยายตัวของหน้าท้อง และพันธุกรรม

อาการทางคลินิกของรอยแตกลายที่เกิดขึ้น มักเป็นหลายตำแหน่ง เป็นสองฝั่งเท่ากัน อาการนี้เป็นปัญหาทางด้านความสวยงาม แต่โอกาสจะเกิดแผลน้อยมาก แบ่งเป็น 2 ระยะ

ระยะที่ 1 ระยะรอยแดง เริ่มต้นจะแสดงอาการเป็นรอยแดงถึงม่วง นูนขึ้นเป็นเส้นตรง มีอาการคันบ้างเล็กน้อย

ระยะที่ 2 ระยะรอยขาว เมื่อเวลาผ่านไป สีแดงม่วงจะค่อยๆจางลง รอยนูนขึ้นก็จะยุบตัวลง ลักษณะของผิวหนังภายนอกจะเห็นเป็นริ้วรอยเล็กๆ ส่วนใหญ่จะเป็นรอยถาวร และส่วนน้อยจะค่อยๆจางไป

หญิงตั้งครรภ์มักพบรอยแตกลายส่วนใหญ่ที่บริเวณหน้าท้อง และพบน้อยบริเวณเต้านมและต้นขา พบในหญิงตั้งครรภ์ที่มีอายุน้อยมากกว่าอายุมาก

การรักษารอยแตกลายในปัจจุบันมีหลายวิธีที่ช่วยให้รอยแตกลายจางลง และมีขนาดเล็กลง แต่ยังไม่มีวิธีการใดที่สามารถรักษาหายเป็นปกติ วิธีการรักษาแบ่งเป็น 2 ประเภทใหญ่ๆ ได้แก่

1. การรักษาโดยการใช้ยาทา และการลอกผิวหนังด้วยสารเคมี

1) ยาทากลุ่มอนุพันธ์ของวิตามินเอ ข้อเสียของการรักษาด้วยวิธีนี้คือ ไม่สามารถใช้ในหญิงตั้งครรภ์ได้ เนื่องจากยาทากลุ่มอนุพันธ์ของวิตามินเอมีผลต่อทารกในครรภ์

2) การลอกผิวหนังด้วยสารเคมี ข้อเสียและผลข้างเคียงของการรักษาด้วยวิธีนี้คือ อาจทำให้เกิดรอยแดง ผิวหนังคัน ลอกเป็นสะเก็ด และเพิ่มความไวต่อตัวกระตุ้นแก่ผิวหนัง นอกจากนี้ยังก่อให้เกิดผื่นภูมิแพ้ต่อสารนั้นๆด้วย

2. การรักษาโดยใช้เครื่องมือ เช่น การกรอผิว หรือการประยุกต์ใช้เลเซอร์ชนิดต่าง ๆ

โดยทั่วไปการรักษารอยแตกลาย (ระยะรอยแดง) คือ ยาทากลุ่มอนุพันธ์ของวิตามินเอ แต่เนื่องจากยากลุ่มนี้ไม่สามารถใช้ในหญิงตั้งครรภ์ได้ จึงมีการศึกษาการป้องกันภาวะท้องลายจากการตั้งครรภ์ โดยการใช้ยาทาสมุนไพรซึ่งเป็นอีกทางเลือก มีข้อดีคือ ภาวะแทรกซ้อนน้อยกว่า และราคาถูกกว่าเมื่อเทียบกับเลเซอร์และการลอกผิวหนังด้วยสารเคมี จึงเป็นที่มาของการศึกษาน้ำมันในพืช ซึ่งมีวิตามินอีเป็นส่วนประกอบ และวิตามินอีมีส่วนช่วยในการเสริมสร้างคอลลาเจน จากข้อมูลปริมาณวิตามินอี พบว่าในน้ำมันดอกทานตะวันมีวิตามินอีมากที่สุด จึงเป็นที่มาของการศึกษาเรื่องประสิทธิภาพของน้ำมันดอกทานตะวันในการป้องกันภาวะท้องลายจากการตั้งครรภ์

4. สถานที่และระยะเวลาในการวิจัย

โรงพยาบาลพระนั่งเกล้า จังหวัดนนทบุรี ระยะเวลาเข้าร่วมโครงการ 22 สัปดาห์ หรือจนกระทั่งใกล้คลอด

5. รายละเอียดที่ปฏิบัติต่ออาสาสมัคร

5.1 เกณฑ์การคัดเลือกอาสาสมัครเข้าร่วมโครงการวิจัย

1. หญิงตั้งครรภ์ท้องแรกอายุ 18 ปีขึ้นไป ไม่เกิน 40 ปี
2. อายุครรภ์อยู่ระหว่าง 16 ถึง 18 สัปดาห์

3. ดัชนีมวลกายอยู่ระหว่าง 18.5 ถึง 25 กิโลกรัม/เมตร^2

4. ไม่ได้รับยาสเตียรอยด์ ทั้งแบบรับประทานหรือทาเฉพาะที่ภายใน 3 เดือนก่อนการรักษา

5. ไม่ได้รับประทานอนุพันธ์ของกรดวิตามินเอภายใน 6 เดือนก่อนการรักษา หรือไม่ได้ทาอนุพันธ์ของกรดวิตามินเอเฉพาะที่ภายใน 3 เดือนก่อนการรักษา

6. ไม่ได้ใช้ยาหรือวิธีใดๆในการกระตุ้นการแบ่งตัวของคอลลาเจน เช่น วิตามินซี

7. ไม่มีประวัติแผลเป็นนูนหรือคีลอยด์บริเวณหน้าท้อง

8. ไม่เป็นผู้สูบบุหรี่

9. ยินยอมเข้าร่วมโครงการวิจัยด้วยความสมัครใจ และลงลายลักษณ์อักษรในใบยินยอมรับการรักษา (Informed consent)

5.2 เกณฑ์การแยกอาสาสมัครออกจากโครงการวิจัย

1. มีความผิดปกติของการสร้างคอลลาเจน เช่น Ehlers-Danlos syndrome
2. มีความผิดปกติทางต่อมไร้ท่อ เช่น Cushing's syndrome
3. มีความผิดปกติของการตั้งครรภ์ เช่น Polyhydramnios
4. มีประวัติการติดเชื้อเริม (Herpes simplex virus)
5. ภูมิคุ้มกันบกพร่อง

5.3 เกณฑ์การให้อาสาสมัครเลิกจากการศึกษาวิจัย

1. ต้องการออกจากการศึกษาวิจัย
2. เกิดภาวะแทรกซ้อนจากการรักษา
3. ได้รับการป้องกันท้องลายด้วยวิธีอื่นๆ นอกเหนือจากที่แพทย์ผู้วิจัยจัดไว้ให้ในระหว่างช่วงการวิจัย

5.4 วิธีการศึกษา

ในงานวิจัยนี้ จะสุ่มอาสาสมัครเป็น 2 กลุ่ม โดยจะสุ่มเลือกการป้องกันท้องแต่ละด้าน กลุ่ม A จะได้รับน้ำมันดอกทานตะวันทาครึ่งท้องด้านขวา และน้ำมันหลอกทาครึ่งท้องด้านซ้าย กลุ่ม B จะได้รับน้ำมันดอกทานตะวันทาครึ่งท้องด้านซ้าย และน้ำมันหลอกทาครึ่งท้องด้านขวา น้ำมันแต่ละขวดจะมีฉลากระบุไว้ว่าให้ทาที่ท้องด้านใด ซึ่งอาสาสมัครจะไม่ทราบว่าทาน้ำมันชนิดใดที่ท้องด้านใด โดยให้ทาทั่วท้องทั้ง 2 ด้าน ทุกวัน เช้าและเย็น หลังอาบน้ำเสร็จ 3 นาที โดยไม่มีการนวดคลึง

สำหรับการติดตามผลการรักษา จะมีการประเมินผลทุก 2 อาทิตย์ จนกระทั่งใกล้คลอด โดยประเมินผลด้วยการใช้ภาพถ่ายจากกล้องถ่ายรูปดิจิตอล เครื่องวัดขนาดความกว้างของท้องลาย และแบบสอบถามประเมินอาการคันและผลข้างเคียงที่เกิดขึ้น ส่วนในด้านความพึงพอใจต่อผลการรักษานั้น จะใช้แบบสอบถามประเมินผลในสัปดาห์ที่ 10 และสัปดาห์ใกล้คลอด

รวมระยะเวลาการเก็บข้อมูลวิจัย 22 สัปดาห์ ตั้งแต่เดือนกันยายน 2556 ถึงเดือนมกราคม 2557 สรุปอาสาสมัครต้องมาโรงพยาบาลพระนั่งเกล้า จังหวัดนนทบุรี ทั้งหมด 12 ครั้ง

6. ประโยชน์ที่คาดว่าจะเกิดขึ้นกับอาสาสมัคร

อาสาสมัครจะได้รับน้ำมัน 2 ชนิด ในการป้องกันภาวะท้องลายจากการตั้งครรภ์ และทำการถ่ายภาพ วัดขนาดความกว้างของท้องลาย และประเมินผลข้างเคียงและความพึงพอใจ ซึ่งประเมินโดยแพทย์ผู้วิจัยโดยไม่เสียค่าใช้จ่ายใดๆ

7. ความเสี่ยงหรือผลข้างเคียง

การทาน้ำมันอาจพบอาการข้างเคียง เช่น แพ้ซึ่งมีอาการคัน ผิวแดง บวมเล็กน้อย บริเวณที่ทำการรักษา แต่มักหายเองได้ แพทย์จะทำการตรวจอาสาสมัครอย่างใกล้ชิด เพื่อดูว่ามีอาการข้างเคียงเกิดขึ้นหรือไม่ หากมีอาการข้างเคียงเกิดขึ้น แพทย์จะทำการรักษาที่เหมาะสมโดยไม่คิดค่าใช้จ่าย

การรักษามีดังต่อไปนี้

1. หยุดการใช้น้ำมันทั้ง 2 ชนิด
2. อาการคัน แดง หรือบวม บริเวณที่ทาน้ำมัน สามารถลดอาการได้โดยการใช้ยาทา Calamine lotion ซึ่งอาการจะดีขึ้นภายในเวลา 3-5 วัน

ในกรณีมีข้อสงสัยเพิ่มเติมเกี่ยวกับการวิจัย อาสาสมัครสามารถติดต่อแพทย์ผู้วิจัยได้ตลอดเวลาที่ แพทย์หญิงณิชา เจนมานะชัยกุล โทรศัพท์ 085-687-6936 E-mail: mzyynj@hotmail.com

8. ขอบเขตการดูแลรักษาความลับของข้อมูลต่างๆของอาสาสมัคร

ข้อมูลต่างๆของอาสาสมัครจะถูกปิดเป็นความลับ ความเป็นส่วนบุคคลจะไม่ถูกเปิดเผยในรายงานหรือผลงานตีพิมพ์ จะเปิดเผยได้เฉพาะในรูปแบบของการสรุปผลการวิจัยเท่านั้น ผู้กำกับดูแลการวิจัยจะได้รับอนุญาตให้ตรวจสอบเวชระเบียนต้นฉบับของอาสาสมัครโดยตรง เพื่อตรวจสอบความถูกต้องของวิธีการดำเนินวิจัยทางคลินิกและหรือข้อมูลอื่นๆ โดยไม่ละเมิดสิทธิของอาสาสมัครในการรักษาความลับเกินขอบเขตที่กฎหมายอนุญาตไว้ โดยอาสาสมัครได้ลงนามใน

เอกสารใบยินยอมอนุญาตให้บุคคลต่างๆข้างต้นมีสิทธิตรวจสอบเวชระเบียนของอาสาสมัครโดยตรง

9. การดูแลรักษาที่ผู้วิจัยจัดให้

อาสาสมัครจะได้รับการตรวจและดูแลอย่างใกล้ชิดโดยแพทย์ผู้วิจัย เพื่อดูว่าเกิดอาการข้างเคียงดังกล่าวหรือไม่ หากมีอาการข้างเคียงเกิดขึ้น แพทย์ผู้วิจัยจะให้การรักษาเพื่อควบคุมอาการข้างเคียงเหล่านี้ จนอาการดังกล่าวหายไปโดยไม่คิดค่าใช้จ่ายใดๆ

10. ค่าตอบแทนอาสาสมัคร และค่ารักษาพยาบาล ค่าชดเชย

หากเกิดความผิดปกติแก่อาสาสมัคร แพทย์ผู้วิจัยจะดูแลรักษาอาสาสมัครจนหายเป็นปกติ โดยอาสาสมัครไม่ต้องเสียค่าใช้จ่าย และได้รับเงินชดเชยกรณีเกิดอาการไม่พึงประสงค์ เป็นจำนวนเงิน 500 บาท เมื่อทราบว่าภาวะแทรกซ้อนนี้เกิดจากงานวิจัย ค่าเสียโอกาสในการทำงาน เป็นจำนวนเงิน 300 บาทต่อวัน จนกระทั่งสามารถทำงานได้

ค่าใช้จ่ายในการเดินทางมาตรวจติดตามผลการรักษา ถ้าตรงกับวันฝากครรภ์ที่อาสาสมัครต้องมาโรงพยาบาลพระนั่งเกล้าอยู่แล้ว ค่าตอบแทนเป็นจำนวนเงิน 200 บาท ในกรณีไม่ตรงกับวันฝากครรภ์ ค่าตอบแทนเป็นจำนวนเงิน 350 บาท

หากอาสาสมัครอยู่ในโครงการตั้งแต่เริ่มจนสิ้นสุดการวิจัย จะมีสิทธิ์รับ Gift voucher เป็นผ้าอ้อมสำเร็จรูปสำหรับเด็กแรกเกิด 1 ชุด

11. สิทธิในการถอนตัวจากโครงการวิจัยของอาสาสมัคร

อาสาสมัครสามารถถอนตัวจากโครงการวิจัยได้ทุกเมื่อ โดยไม่กระทบต่อการดูแลรักษาที่พึงได้รับตามปกติ

12. ข้อพิจารณาด้านจริยธรรม

ในการศึกษาวิจัยนี้ดำเนินการตามหลักของการปฏิบัติการวิจัยทางคลินิกที่ดี (Good Clinical Practice: GCP) ซึ่งเป็นมาตรฐานสากลด้านจริยธรรมและด้านวิชาการสำหรับใช้ในการวางรูปแบบการดำเนินงาน การบันทึกข้อมูลและการเขียนรายงานการศึกษาวิจัยในมนุษย์ การปฏิบัติตามเกณฑ์มาตรฐานนี้เป็นการรับประกันต่อสาธารณชนว่า สิทธิ ความปลอดภัย และความเป็นอยู่ที่ดีของอาสาสมัครจะได้รับการคุ้มครองตามหลักการแห่งคำประกาศเฮลซิงกิ (Declaration of Helsinki) และผลการวิจัยทางคลินิกที่เชื่อถือได้

13. ชื่อ ที่อยู่ โทรศัพท์ ของแพทย์ผู้วิจัย

แพทย์หญิงณิชา เจนมานะชัยกุล

สาขาวิชาตจวิทยา สำนักวิชาเวชศาสตร์ชะลอวัยและฟื้นฟูสุขภาพ

โรงพยาบาลมหาวิทยาลัยแม่ฟ้าหลวง กรุงเทพมหานคร

38/11-13 อาคารอโศกเพลส ถนนอโศก สุขุมวิท 21 แขวงคลองเตยเหนือ เขตวัฒนา

กรุงเทพมหานคร 10110

โทรศัพท์ 085-687-6936

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APPENDIX C

DATA COLLECTION FORM

แบบบันทึกข้อมูลผู้เข้าร่วมโครงการวิจัย

เรื่อง: การศึกษาประสิทธิภาพของน้ำมันดอกทานตะวันในการป้องกันภาวะท้องลายจากการตั้งครรภ์ (The Efficacy of Sunflower Oil in the Prevention of Striae Gravidarum)

ข้อมูลทั่วไป

(ภาษาอังกฤษ) First Name ..... Last Name .....

(ภาษาไทย) ชื่อ ..... นามสกุล .....

อายุ ..... ปี อาชีพ .....

สถานที่ทำงาน .....

ที่อยู่ .....

รหัสไปรษณีย์ ..... โทร ..... มือถือ .....

Fax ..... E-mail .....

1. ข้อมูลเบื้องต้นสำหรับผู้เข้าร่วมโครงการวิจัย (Participant demographic information)

1) อายุครรภ์ (Gestational age) ..... สัปดาห์ (weeks)

2) น้ำหนัก (Weight) ..... กิโลกรัม (kilograms) ส่วนสูง ..... เซนติเมตร (centimeters)
ดัชนีมวลกาย (Body mass index) ..... กิโลกรัม/เมตร^2 (kg/m^2)

3) ระดับการศึกษา (Level of education)

..... ต่ำกว่าปริญญาตรี (Under diploma)

..... ปริญญาตรี (Diploma)

..... สูงกว่าปริญญาตรี (Academic)

4) ประวัติการแท้งบุตร (History of previous abortion)

..... เคย (ระบุ จำนวนบุตรแท้ง) (Yes, Number of abortion) ..... ไม่เคย (No)

5) ประวัติคนในครอบครัวท้องลายจากการตั้งครรภ์ (Family history of striae gravidarum)

..... มี (Yes) ..... ไม่มี (No)

6) ประเภทสีผิว (Fitzpatrick skin type) I II III IV V VI

7) โรคประจำตัว (Underlying disease) .....

8) ประวัติการแพ้ยา (Medical history) .....

2. ท่านมีประวัติข้อใดข้อหนึ่ง ดังต่อไปนี้หรือไม่ (เลือกได้มากกว่า 1 ข้อ)

..... ใช่ ..... ได้รับยาสเตียรอยด์ ทั้งแบบรับประทานหรือทาเฉพาะที่ภายใน 3 เดือนก่อนการรักษา

..... ได้รับประทานอนุพันธ์ของกรดวิตามินเอภายใน 6 เดือนก่อนการรักษา หรือได้ทาอนุพันธ์ของกรดวิตามินเอเฉพาะที่ภายใน 3 เดือนก่อนการรักษา

..... ได้ใช้ยาหรือวิธีใดๆในการกระตุ้นการแบ่งตัวของคอลลาเจน เช่น วิตามินซี

..... มีประวัติแผลเป็นนูนหรือคีลอยด์บริเวณหน้าท้อง

..... สูบบุหรี่

..... มีความผิดปกติของการสร้างคอลลาเจน เช่น Ehlers-Danlos syndrome

..... มีความผิดปกติทางต่อมไร้ท่อ เช่น Cushing's syndrome

..... มีความผิดปกติของการตั้งครรภ์ เช่น Polyhydramnios

..... มีประวัติการติดเชื้อเริม (Herpes simplex virus)

..... ภูมิคุ้มกันบกพร่อง

..... ไม่มีประวัติใดๆข้างต้น

3. ถ่ายรูปท้อง ☐ ตรง ☐ ซ้าย 45° ☐ ขวา 45°

Experiment Record Data Sheet

1. Severity of Striae Gravidarum Score

No striae	=	0	No erythema	=	0
< 5 Striae	=	1	Mild erythema (light pink or red)	=	1
5-10 Striae	=	2	Marked erythema (dark red)	=	2
> 10 Striae	=	3	Violaceous erythema (purple)	=	3

The abdomen is divided into four quadrants. In each quadrant, striae are scored up to a maximum of 6; a score of 0 to 3 for the number of striae and a score of 0 to 3 for the degree of erythema. The maximum total score for each side of the abdomen is 12.

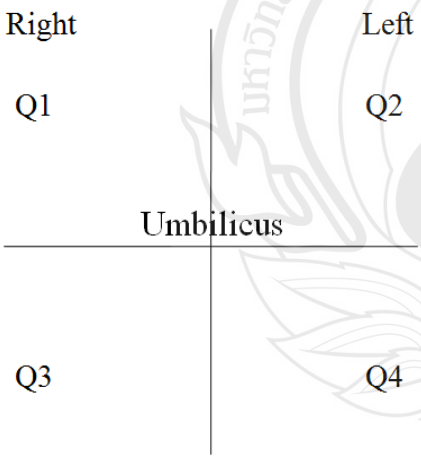
A total score of 1 to 3 represents “no significant striae”.

A total score of 4 to 6 represents “mild striae”.

A total score of 7 to 9 represents “moderate striae”.

A total score of 10 to 12 represents “severe striae”.

Modified from (Atwal et al., 2006)



Number of striae / Degree of erythema		Week 2	Total	Week 4	Total	Week 6	Total	Week 8	Total
Right	Q1								
	Q3								
Left	Q2								
	Q4								

Number of striae / Degree of erythema		Week 10	Total	Week 12	Total	Week 14	Total	Week 16	Total
Right	Q1								
	Q3								
Left	Q2								
	Q4								

Number of striae / Degree of erythema		Week 18	Total	Week 20	Total	Week 22	Total
Right	Q1						
	Q3						
Left	Q2						
	Q4						

In Summary

Total	Week 2	Week 4	Week 6	Week 8	Week 10	Week 12	Week 14	Week 16	Week 18	Week 20	Week 22
Right											
Left											

2. Measurement the Width of Striae Gravidarum

		Week 2	Week 4	Week 6	Week 8	Week 10	Week 12
1	Right						
	Left						
2	Right						
	Left						
3	Right						
	Left						
Average	Right						
	Left						

		Week 14	Week 16	Week 18	Week 20	Week 22
1	Right					
	Left					
2	Right					
	Left					
3	Right					
	Left					
Average	Right					
	Left					

3. ภาพถ่ายท้องลายโดยรวมประเมินโดยแพทย์ (Global Photographic Score)

ตารางนี้สำหรับแพทย์อีก 3 ท่าน ที่ไม่มีส่วนเกี่ยวข้องกับการวิจัยเป็นผู้ประเมินเท่านั้น โดยประเมินจากภาพถ่ายท้องลายแต่ละด้านในสัปดาห์ใกล้คลอดเทียบกับก่อนการรักษา โดยให้คะแนนดังเกณฑ์ต่อไปนี้

-3 = ลดลงอย่างมาก
-2 = ลดลงปานกลาง
-1 = ลดลงเล็กน้อย
0 = ไม่เปลี่ยนแปลง
1 = เพิ่มขึ้นเล็กน้อย
2 = เพิ่มขึ้นปานกลาง
3 = เพิ่มขึ้นอย่างมาก

Global photographic score (-3 to +3)		At delivery		
		Physician 1	Physician 2	Physician 3
	Right			
	Left			

4. แบบประเมินความพึงพอใจ (Participant Satisfaction)

คะแนนความพึงพอใจในการรักษา มีค่าตั้งแต่ 0% ถึง 100%

0%-20% = ได้ผลค่อนข้างน้อย

20%-40% = ได้ผลน้อย

40%-60% = ได้ผลปานกลาง

60%-80% = ได้ผลค่อนข้างมาก

80%-100% = ได้ผลดีมาก

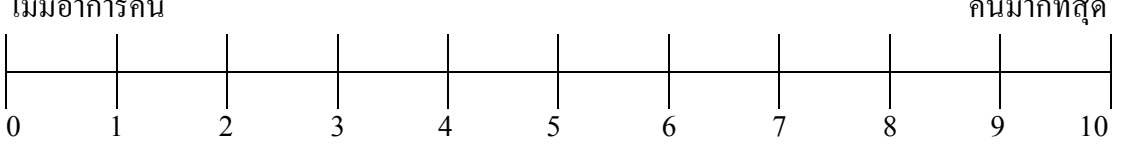
		Week 10	At delivery
Satisfaction (%)	Right		
	Left		

5. แบบประเมินอาการคัน (Pruritus Score)

คะแนนอาการคัน มีค่าตั้งแต่ 0 ถึง 10

โดยที่ 0 คือ ไม่มีอาการคัน 10 คือ คันมากที่สุด

		Week 2	Week 4	Week 6	Week 8	Week 10	Week 12	Week 14	Week 16	Week 18	Week 20	Week 22
Pruritus score	Right											
	Left											



6. แบบประเมินผลข้างเคียง (Side Effects)

		Week 2	Week 4	Week 6	Week 8	Week 10	Week 12	Week 14	Week 16	Week 18	Week 20	Week 22
Side effects	Right											
	Left											

APPENDIX D

RESEARCH PARTICIPANTS

No striae

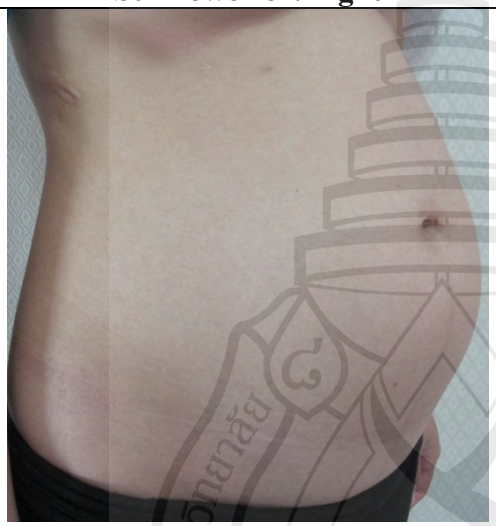
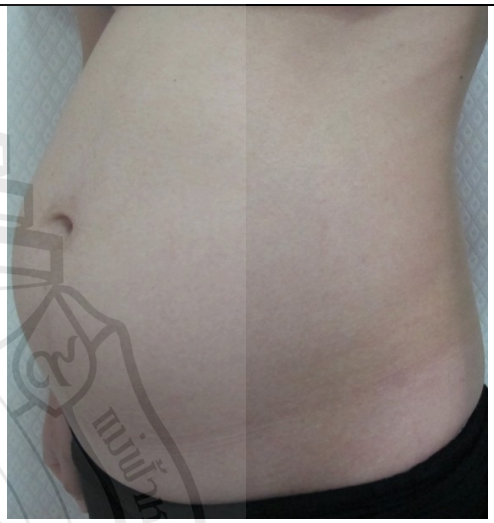
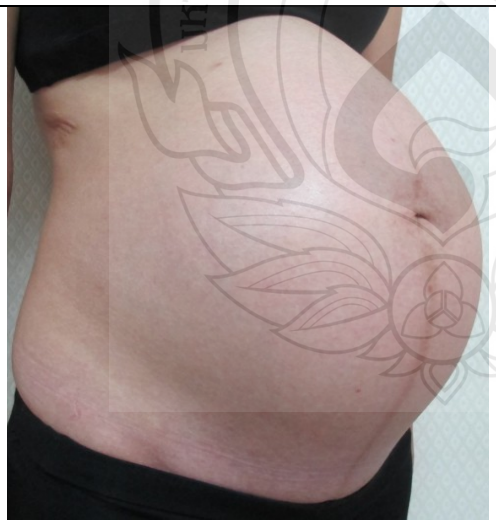
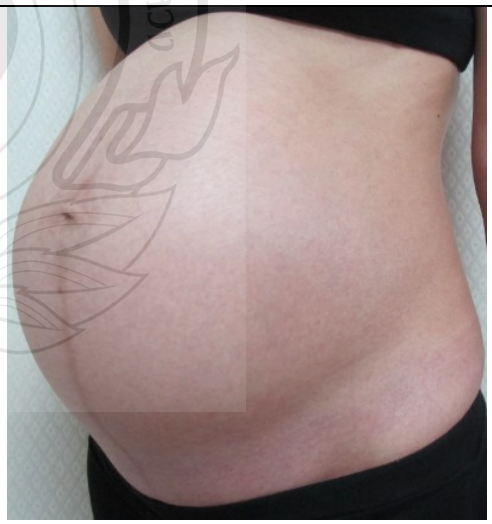
1	Sunflower oil/Right	Placebo/Left
Before intervention		
After intervention		

Figure D1 Before Intervention and After Intervention of Sunflower Oil Group and Placebo Group

No significant striae

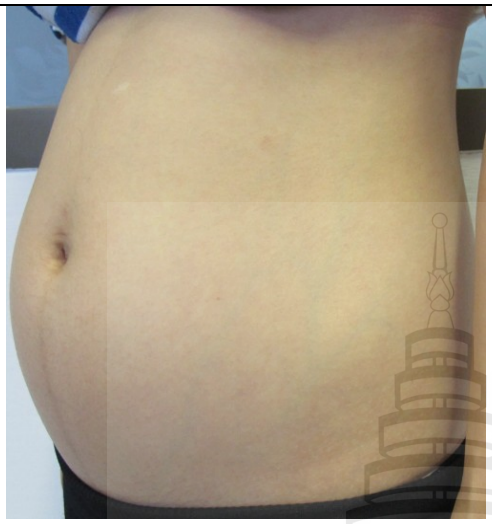
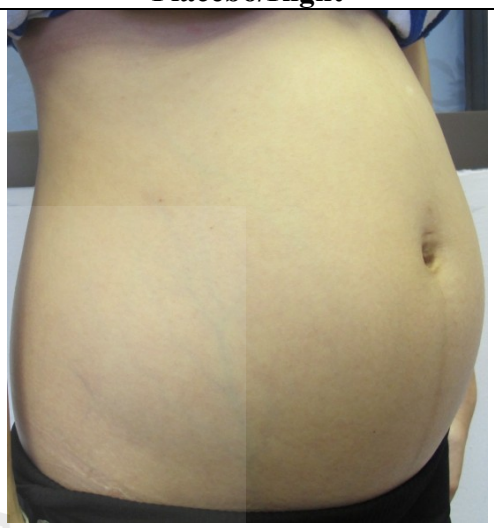
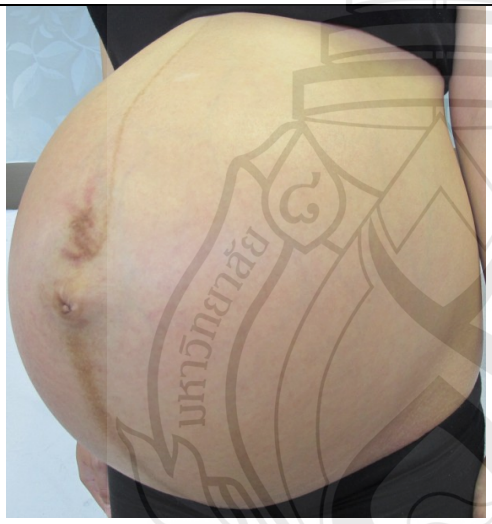
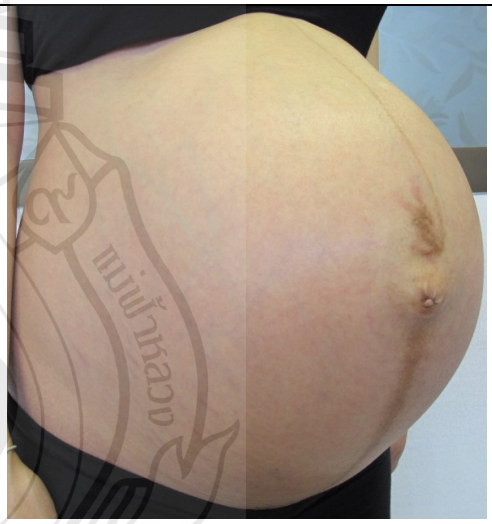
2	Sunflower oil/Left	Placebo/Right
Before intervention		
After intervention		

Figure D2 Before Intervention and After Intervention of Sunflower Oil Group and Placebo Group

Mild striae

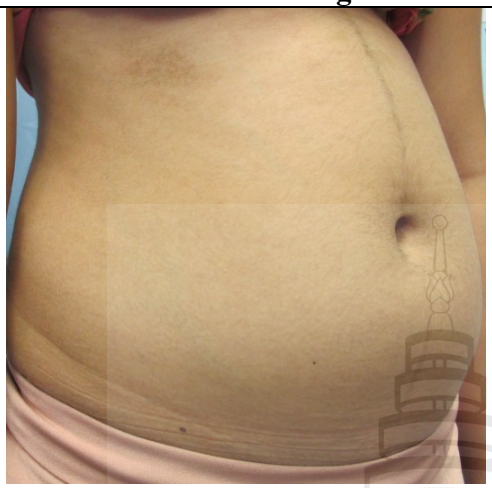
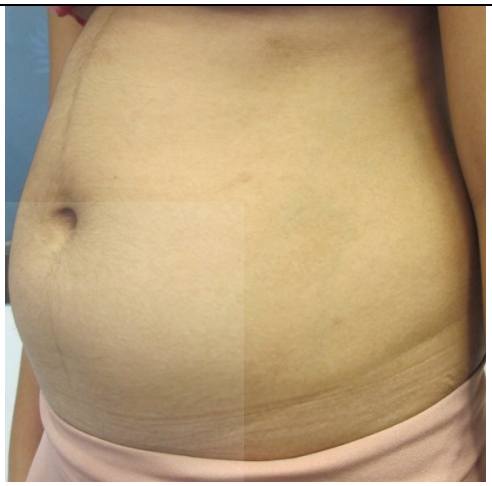
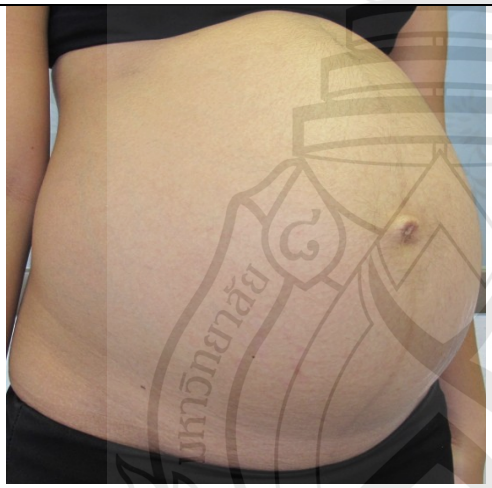
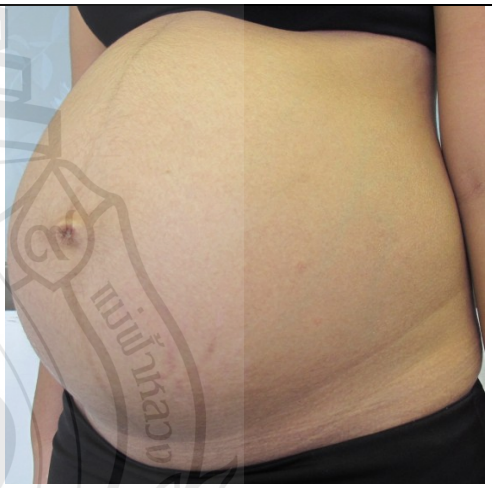
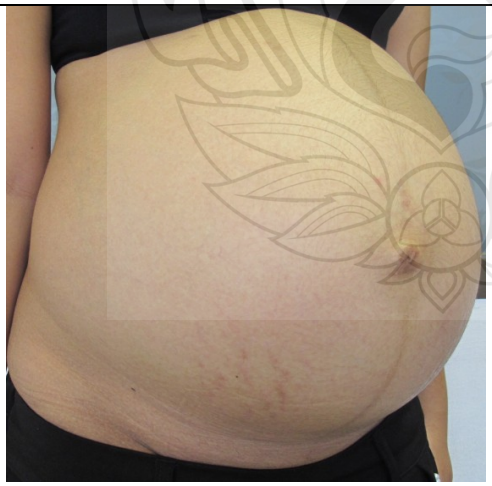
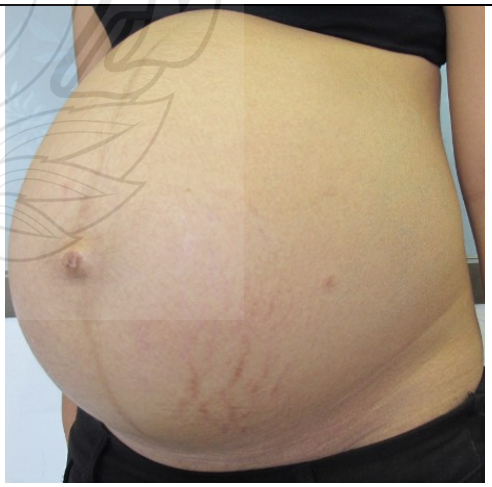
3	Sunflower oil/Right	Placebo/Left
Before intervention		
Onset of striae		
After intervention		

Figure D3 Before Intervention, Onset of Striae and After Intervention of Sunflower Oil Group and Placebo Group

Moderate striae

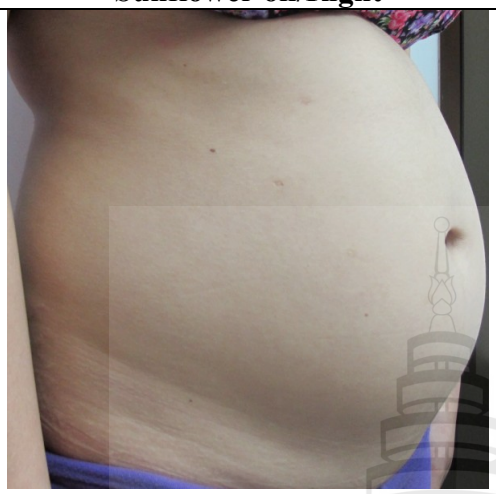
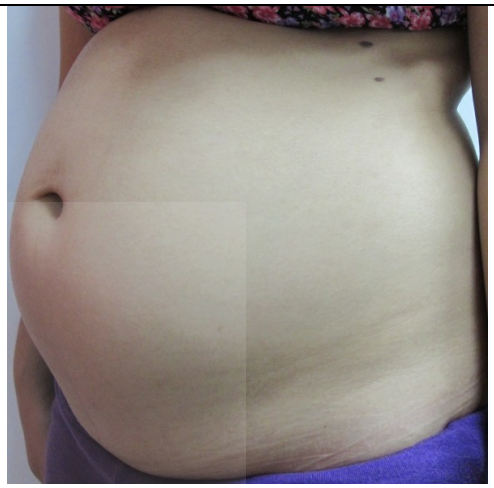
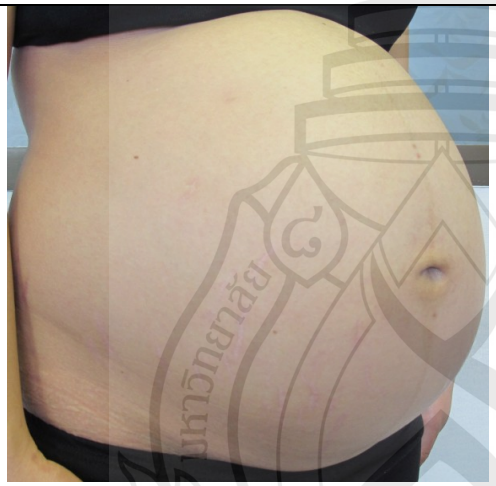
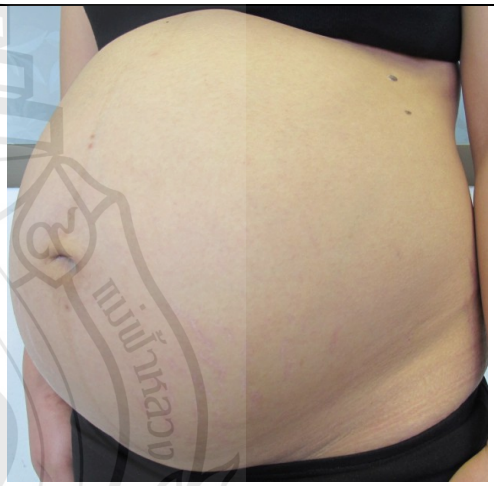
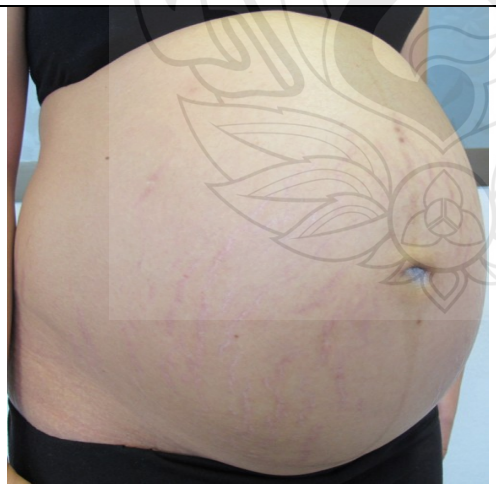
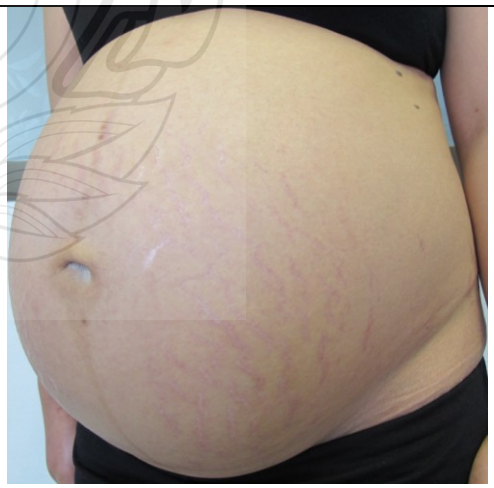
4	Sunflower oil/Right	Placebo/Left
Before intervention		
Onset of striae		
After intervention		

Figure D4 Before Intervention, Onset of Striae and After Intervention of Sunflower Oil Group and Placebo Group

Severe striae

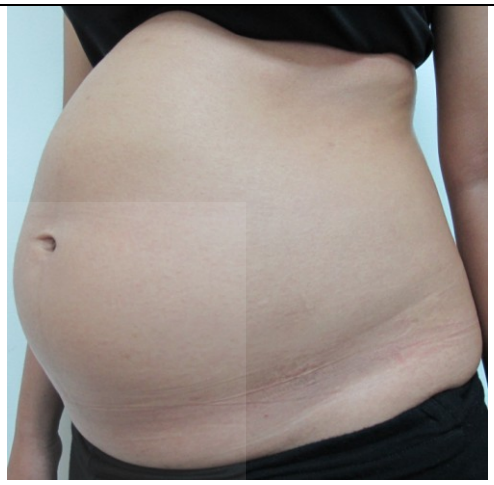
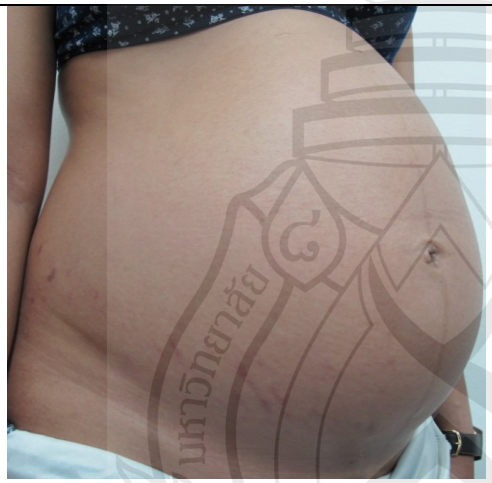
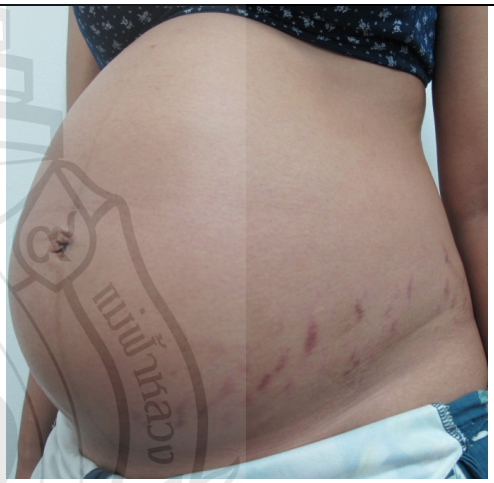
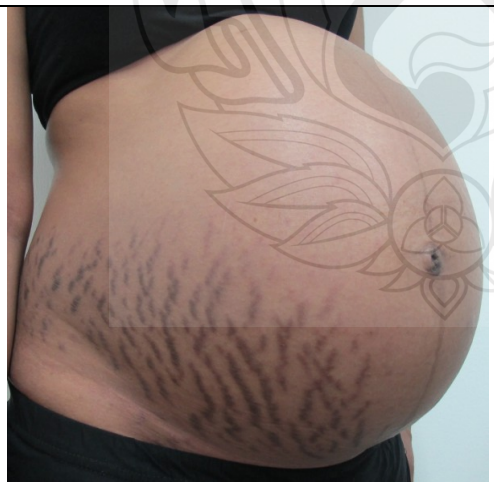
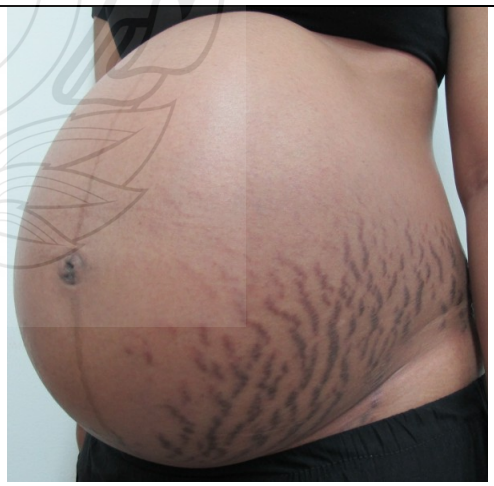
5	Sunflower oil/Right	Placebo/Left
Before intervention		
Onset of striae		
After intervention		

Figure D5 Before Intervention, Onset of Striae and After Intervention of Sunflower Oil Group and Placebo Group

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