EFFECTIVENESS OF THE COMBINATION TREATMENT OF KOREAN RED GINSENG AND VITAMIN B5 IN ANDROGENETIC ALOPECIA

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IN
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THIS THESIS IS A PARTIAL FULFILLMENT OF
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Phoe Pyi

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Author	Phoe Pyi
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ABSTRACT

Background: Androgenetic alopecia (AGA) is a common hair loss disorder affecting both men and women, primarily due to dihydrotestosterone (DHT)-induced hair follicle miniaturization. While conventional treatments such as minoxidil and finasteride have been used, their side effects necessitate alternative therapeutic options. Korean Red Ginseng (KRG) and Vitamin B5 have been recognized for their potential hair-regenerative properties.

Objective: This study aims to evaluate the effectiveness and safety of a combination treatment of Korean Red Ginseng and Vitamin B5 in managing androgenetic alopecia.

Methods: A quasi-experimental clinical study was conducted on 12 male participants aged 25-45 years with AGA (Hamilton-Norwood Type I-III). Participants applied a topical hair lotion containing Korean Red Ginseng and Vitamin B5 twice daily for 12 weeks. Hair count was assessed using a Trichoscope at baseline, 4th, 8th, and 12th weeks. The Modified Global Photographic Assessment (MGPA) Score and Patient Satisfaction Score were used to evaluate improvement and satisfaction. Adverse effects were monitored throughout the study.

Results: The mean hair count increased significantly from baseline (19.75 ± 1.35) to the 12th week (22.08 ± 2.23) ($p < 0.001$). MGPA scores showed a steady improvement, with significant differences observed at the 12th week compared to baseline ($p = 0.021$). Patient satisfaction scores improved significantly over time ($p = 0.005$), with 66.7% of participants reporting satisfaction by the 12th week. No adverse effects were recorded during the study period.

Conclusion: The combination of Korean Red Ginseng and Vitamin B5 demonstrated significant improvements in hair count, scalp coverage, and patient satisfaction, with no reported adverse effects. This suggests that it may serve as a safe and effective alternative treatment for androgenetic alopecia. Further research with a larger sample size and extended follow-up is recommended to validate these findings.

Keywords: Androgenetic Alopecia, Korean Red Ginseng, Vitamin B5, Hair Growth, Alternative Treatment, Hair Count

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INTRODUCTION

1.1 Background and Rationale

Nowadays, alopecia becomes a common problem for both men and women (Truong & Jeong, 2021). Roughly, 60% of men undergo androgenetic alopecia by 50 years of age. The risk is raised up to 80% by 70 years of age and more. Although androgenetic alopecia occurs in a considerable population, the frequency and severity are found to be reduced in women than in men (Kang, 2019).

Among all types of alopecia, androgenetic alopecia (AGA) is the most commonly seen. It is a chronic condition in which hair loss is gradual and progressive which is principally seen in a person who has a strong genetic history. Dihydrotestosterone (DHT) which promotes hair miniaturization plays a vital role in the pathophysiology of androgenetic alopecia (Melo et al., 2020). The treatment is still quite challenging for dermatologists (Kelly et al., 2016). Currently, minoxidil (MNX) and finasteride are mainly used for alopecia patients although their effects are transient. Many scientists and dermatologists are emphasizing the research process to create new treatment options for both preventing and treating hair loss (Truong & Jeong, 2021).

Ginseng has been used to fill up vital energy as a preventive measure in traditional Chinese medicine (Murata et al., 2012). Korean Red ginseng (*Panax ginseng* C. A. Meyer) is one of the popular ginsengs that has been used in Asian countries for a long time (Truong & Jeong, 2021). There are so many research papers for ginseng, proving that it has more than 30 ginsenosides and active triterpene (Murata et al., 2012).

Recent studies discovered that Korean Red ginseng comprised a large amount of ginsenosides which are Rb1, -Rb2, -Rc, -Rd, -Rg3, -Rg1, and -Ro. These ginsenosides are primarily responsible for biological activities, including antioxidant, antitumor, antidiabetic, anti-inflammatory, and hepatoprotective effects. The ginsenoside-Rb1 and -Rg3 have already been demonstrated their action of enhancing hair growth in cultured human hair follicles. Many clinical trials have already stated that oral taking of Korean Red ginseng improves hair length and density in alopecia patients (Truong & Jeong, 2021).

Korean Red ginseng causes hair dermal papilla cell proliferation and increases βcatenin, p-GSK-3β, cyclin D1, and cyclin E, indicating that Korean Red ginseng encourages hair regeneration and rapid changing of the telogen phase to anagen phase. Moreover, Korean red ginseng exerts an effect on ERK and Akt pathways which involve in transcription factors activation including β-catenin for new hair formation (Truong & Jeong, 2021).

D-panthenol, pro-vitamin B5, is famous for its anti-inflammatory, skin renewing, and hydration effects. D-panthenol has been used in so many hair care products for hair growth and anti-hair loss. There were previous studies that stated that oral D-panthenol taking can improve both female pattern hair loss and male androgenetic alopecia (Shin et al., 2021). The two factors involved in the formation of androgenetic alopecia which are free radical oxygen species and follicular inflammation can be inhibited by D-panthenol (Kutlu, 2020)

D-panthenol raises the keratin-associated protein 4 expression which takes part in hair cortex keratinization. Thus, it promotes strong hair formation (Melo et al., 2020). D-panthenol can re-grow the hair by following mechanisms. First of all, it can inhibit apoptosis and restrain from the senescence in dermal papilla cells & outer root sheet cells in turn promoting epithelial cell proliferation. D-panthenol can maintain and prolong the anagen phase by enhancing alkaline phosphatase, versican, and Wnt/βcatenin signaling pathway. It can also support hair growth by inhibiting catagen formation (Shin et al., 2021).

Korean Red Ginseng & Vitamin B5 are safe, costly, and easily accessible agents throughout the world. The mechanisms of red ginseng and vitamin B5 in androgenetic alopecia have not been fully documented. Additionally, there is no previous research study for the combination of Korean Red Ginseng and Vitamin B5 used as an androgenetic alopecia treatment. Therefore, studying the effectiveness and safety of the combination treatment of Korean Red Ginseng and Vitamin B5 is the main aim of this study.

1.2 Research Question

Is the combination treatment of Korean Red ginseng (*Panax ginseng*) and Vitamin B5 considered as a safe and effective treatment for androgenetic alopecia?

1.3 Objective

1.3.1 General Objective

To study the effectiveness and safety of the combination treatment of Korean Red ginseng (*Panax ginseng*) and Vitamin B5 in androgenetic alopecia.

1.3.2 Specific Objective

1.3.2.1 Primary Outcome

To compare average mean changes of hair count from baseline to 4th, 8th, and 12th week by Trichoscope.

1.3.2.2 Secondary Outcome

1. To assess overall improvement and patient satisfaction by using the Modified Global Photographic Assessment Score and Patient's Satisfaction Score.
2. To assess the adverse reactions of the combination treatment of Korean Red ginseng (*Panax ginseng*) and Vitamin B5 by using a research questionnaire.

1.4 Hypothesis

1.4.1 Primary Hypothesis

The combination treatment of Korean Red ginseng (*Panax ginseng*) and Vitamin B5 is effective in the treatment of androgenetic alopecia by increasing the hair count.

1.4.2 Secondary Hypothesis

The combination treatment of Korean Red ginseng (*Panax ginseng*) and Vitamin B5 can be used safely, measured by assessing the adverse effects that occurred during treatment.

1.5 Conceptual Framework

In androgenetic alopecia, hair loss is especially due to the action of male hormones, which is a key regulator of hair development. In the patient with androgenetic alopecia, active enzyme 5α-Reductase is higher than in a non-balding person. 5α-Reductase enzyme catalyzes the male hormone testosterone to dihydrotestosterone DHT which is involved in the signaling pathway of androgen receptors in hair follicles and responsible for androgen-induced miniaturization of hair. In addition, DHT also upregulates the growth factor TGF-β in hair dermal papilla cells which then activates the cellular apoptotic pathway and suppresses the development of hair. In addition, upregulated TGF-β pathway also induces the transition of the hair cycle into the catagen phase and increases hair loss.

By using Korean Red ginseng and D-panthenol which is a pro-vitamin B5, the pathogenesis of the androgenetic alopecia can be prevented and reversed. The activity of the enzyme 5α-Reductase is downregulated by ginsenosides of Korean Red ginseng which consequently suppress the activity of dihydrotestosterone. Additionally, with the combined effects of D-panthenol and Korean Red ginseng, the infamous TGF-β pathway that causes multiple pathogenesis of hair loss can be prevented. The inflammation of hair follicles that resulted from TGF-β can be suppressed by D-panthenol. Furthermore, Korean Red ginseng and D-panthenol have properties that can generate hair growth and anti-apoptosis of the hair follicles. Because of all the above mechanisms, the combination of Korean Red ginseng and D-panthenol can be used as an alternative treatment for androgenetic alopecia.

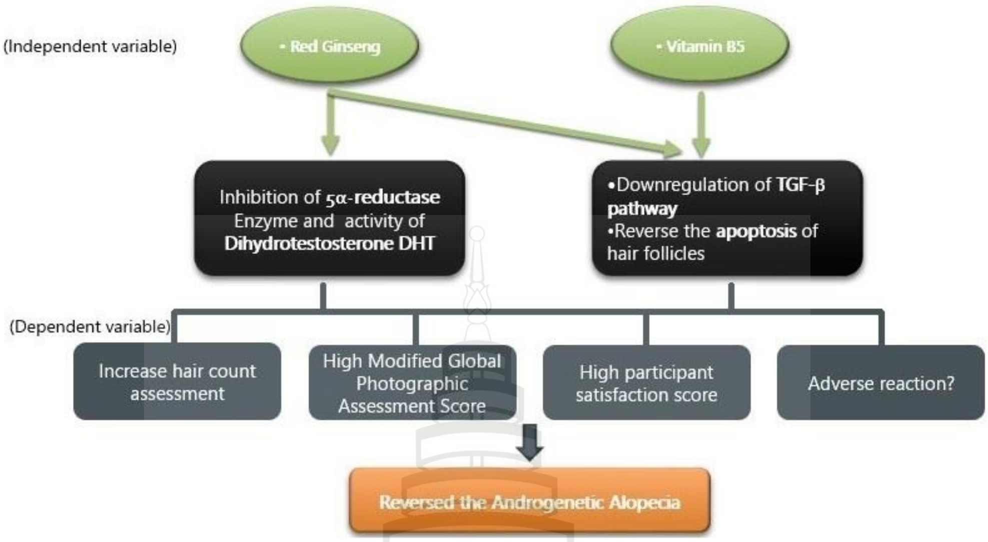

Figure 1.1 Conceptual framework

1.6 The Scope of Research

Twelve participants of males who are willing to treat androgenetic alopecia with Hamilton Norwood classification of Type I – III, age 25-40 years will be done for the combination treatment of Korean Red Ginseng and Vitamin B5.

Volunteer received treatment of androgenic alopecia with hair serum containing Korean Red ginseng and vitamin B5 twice a day for 3months and effective and safety will be assessed on 4th, 8th, and 12th week at Mae Fah Luang Hospital Bangkok.

Modified Global Photographic Assessment Score Hair count (Hair density) assessment with trichoscope will be done at baseline and follow-up visit on 4th, 8th, 12th week after the last treatment session under the same digital camera setting. All adverse effects were recorded with a research questionnaire.

1.7 Operation Definition

1.7.1 Androgenetic (AGA) Definition

Androgenetic alopecia (AGA) is an insidious loss of hair follicles which is a chronic progressive, non-cicatricial and mainly due to male hormonal response. Pathogenesis of androgenetic alopecia is multifactorial and polygenic.

1.7.2 Effectiveness

The effectiveness of the treatment is regarded as any conditions of improvement of the hair loss condition such as regrowth of the hair follicles in baldness areas, increase hair density (hair counts), delay occurrence, and prevention of hair loss.

1.7.3 Hair Count (Hair Density) Assessment

Hair count (hair density) is evaluated as the number of hair strands in $1cm^2$ by using with trichoscope.

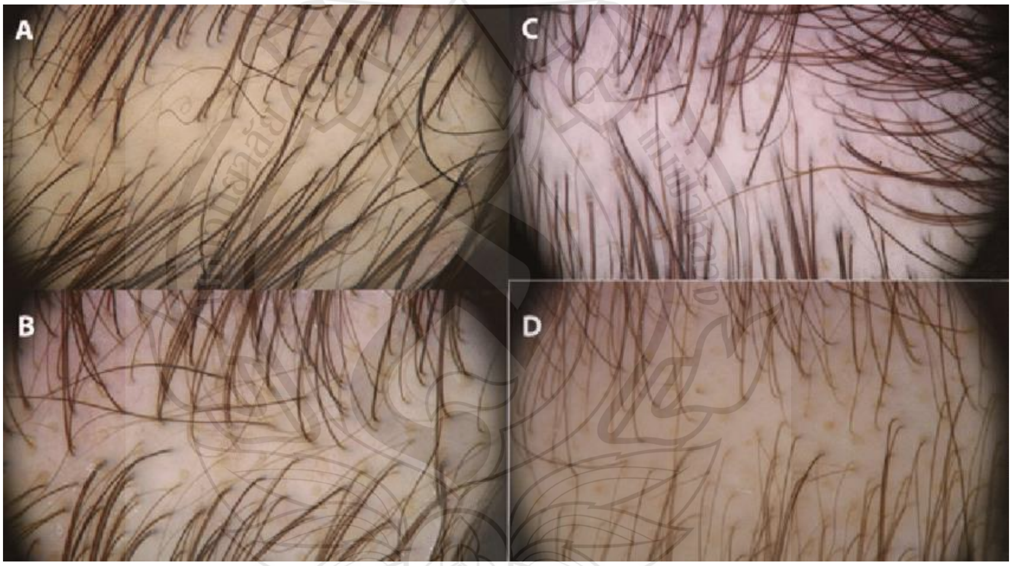

Figure 1.2 Assessment of hair count by Trichoscope

1.7.4 Adverse Effects

Although the topical adverse reactions from Korean Red ginseng and D-panthenol are rarely reported, the expected adverse effects including allergic contact dermatitis, anaphylactic reactions, and exacerbation of pre-existing allergic conditions should be observed.

1.7.5 Hamilton - Norwood Classification (Male Pattern)

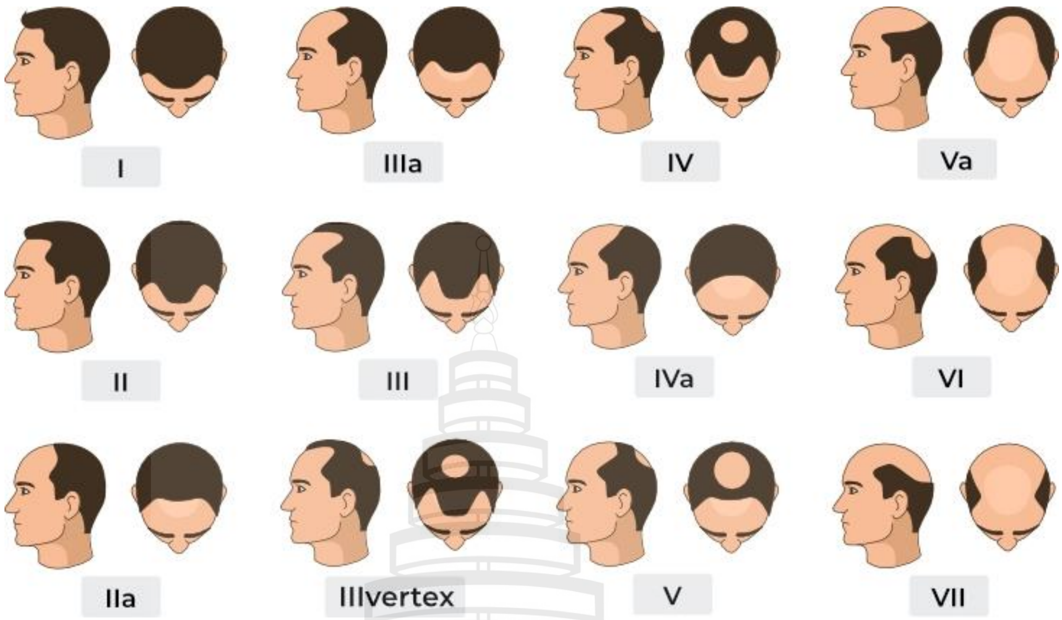

Figure 1.3 Hamilton-Norwood classification of androgenetic alopecia

1.7.6 Participant Satisfaction Score

Table 1.1 Participant satisfaction score

Grade	Degree
-1	Unsatisfied
0	No difference
1	Somewhat satisfied
2	Moderately satisfied
3	Very satisfied
4	Completely satisfied

1.7.7 Modified Global Photographic Assessment Score (MGPA Score)

Table 1.2 Modified global photographic assessment score (MGPA score)

MGPA point	Degree
1	Significant disease progression
2	Moderate disease progression
3	Minimal disease progression

Table 1.2 (continued)

MGPA point	Degree
4	No change
5	Slight improvement
6	Moderate improvement
7	Significant improvement

Note Baseline MGPA = 4

Photographic must be taken in 2 positions; Vertex & forehead.

Figure 1.4 Two different position of hair assessment for modified global photographic assessment score

CHAPTER 2

REVIEW OF RELATED LITERATURE

Hair, a vital skin appendage, arises from hair follicles and has numerous functions which include protective function, thermoregulatory function, sensory, and tactile activities, and cosmetic appearance. Nowadays, the incidence of hair loss has drastically increased not only in older people but also in young people. It can result in psychological stress although alopecia is not a life-threatening disease

2.1 Hair Anatomy

Hair follicles are mainly composed of 2types of cells; epithelial cells and dermal papilla cells. The special components of the hair follicle which are dermal papilla cells and outer root sheath cells have a crucial role in hair follicle morphogenesis and regeneration. Dermal papilla cells induce surrounding epithelial cells to proliferate and differentiate into layers of the hair shaft and the channel surrounding the hair shaft by secreting the insulin-like growth factor-1 (IGF-1), vascular endothelial growth factor (VEGF) and keratinocyte growth factor (KGF). This occurs during the anagen phase. The size and shape of hairs are mainly influenced by dermal papilla cells. Therefore, the anti-apoptotic and proliferative potencies of these cells are the major determinant for anti-hair loss treatment (Kang, 2019; Truong & Jeong, 2021; Shin et al., 2021).

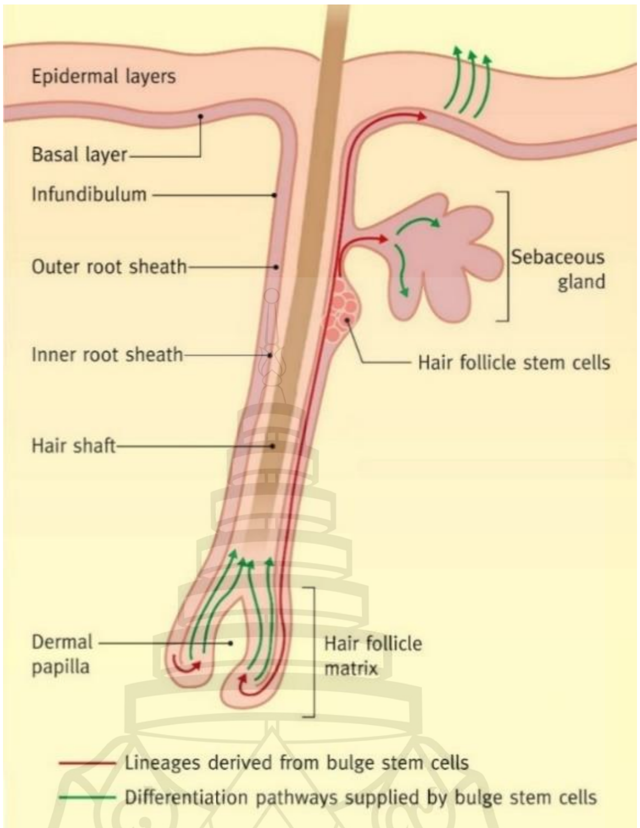

Figure 2.1 Structure of hair

Hair follicles are regenerated throughout the entire life by repeating cycles which include anagen (growth phase), catagen (regression phase), and telogen (resting phase). The majority of the hair cycle is occupied in the anagen phase, which mainly determined the length of the hair shaft. In this phase, hair follicles undergo continuous cell proliferation and differentiation. The abnormal rest of the anagen phase can lead to gradual hair thinning. In the catagen and telogen phase, cells from the lower part of the hair follicle undergo apoptosis and result in hair follicle shrinkage and hair shaft loss. Additionally, alkaline phosphatase in dermal papilla cells serves as a marker for hair follicle neogenesis and telogen-to-anagen transition (Truong & Jeong, 2021; Shin et al., 2021).

2.2 Androgenetic Alopecia

Androgenetic alopecia (AGA) is a gradual loss of hair follicles which is a chronic progressive stage, mainly due to androgen. It is commonly seen in patients with a genetic history of androgenetic alopecia. It can be found not only in men but also in females (Melo et al., 2020). There is a strong paternal influence on the risk of balding (Kang, 2019).

2.2.1 Pathophysiology

The pathophysiology of androgenetic alopecia is mainly due to multifactorial and polygenic. Male androgenetic alopecia is largely determined by the influence of hormones on hair follicles and genetic factors, although the mode of inheritance is uncertain. But for female androgenetic alopecia, the etiology is still less known (Dawid-Pać et al., 2014; Kang, 2019; Kelly et al., 2016).

Firstly, the male hormone dihydrotestosterone – DHT and the activity of the 5α-Reductase – 5αR enzyme take part in a crucial role in androgenetic alopecia, especially in males (Bolognia, 2012). 5α-Reductase (5αR) reduces testosterone to dihydrotestosterone (DHT), which is higher in androgenetic alopecia than in non-balding individuals (bolonia + Murata). In humans, there are 3 types of 5αR isoenzymes – types I, II, and III. Type I 5αR is mainly found in the liver, prostate, and non-genital skin whereas type II 5αR is mainly expressed in hair papilla cells, which is closely related to hair growth. But for Type III 5αR, the activity is not fully known although these isoenzymes are mostly found in the epidermis and dermis (Bolognia, 2012; Murata et al., 2012). DHT bind with the androgen receptor, the receptor complex undergoes enzymatic transformations, and then, it binds to specific locations in active genes in hair papilla cells resulting in hair follicles miniaturization by cytokine secretion (Dawid-Pać et al., 2014). However, in female pattern androgenetic alopecia, the androgen role is not well documented (Kang, 2019). Development of androgenetic alopecia after puberty, or during the perimenopausal and menopausal periods may be associated with strong genetic factors, systemic hormonal changes, and alteration of androgen levels at the level of hair follicles.

Additionally, genes for the androgen receptor (AR), histone-deacetylases (HDAC) 4 and 9, and WNT10A are strongly associated with the development of hair follicles (Kang, 2019). Histone-deacetylases HDACs have a great role in androgen receptor signaling that is responsible for androgen-induced hair follicle miniaturization in androgenetic alopecia (Heilmann-Heimbach et al., 2016). In a patient with androgenetic alopecia, expression of WNT10 protein is lowered which can interfere with the WNT signaling for hair growth (Heilmann et al., 2013).

Moreover, increased reactive oxygen species and nitric oxide that are produced from the activity and metabolism of androgens are responsible for the pathogenesis of androgenetic alopecia. Microscopic follicular inflammation is also involved the in the pathogenesis of androgenetic alopecia (Kutlu, 2020). Several signaling molecules such as transforming growth factor (TGF)-β1 and β2, dickkopf 1 (a member of the WNT signaling family), and interleukin-6 inhibit hair growth in androgenetic alopecia. Both prostaglandin D2 synthase and prostaglandin D2 are found to be elevated in balding scalp skin showing that it has an inhibitory effect on hair growth (Kang, 2019).

2.2.2 Types of Androgenetic alopecia

2.2.2.1 Male pattern, Hamilton Norwood type

This type of clinical pattern is largely contributed to men, and occasionally to women. The frontal hairline is first recessed in a triangular pattern which is the typical finding. Then the progressive vertex thinning with a completely bald scalp follows. Mostly the occipital area and sides of the scalp are not affected even in long-standing androgenetic alopecia (Kang, 2019).

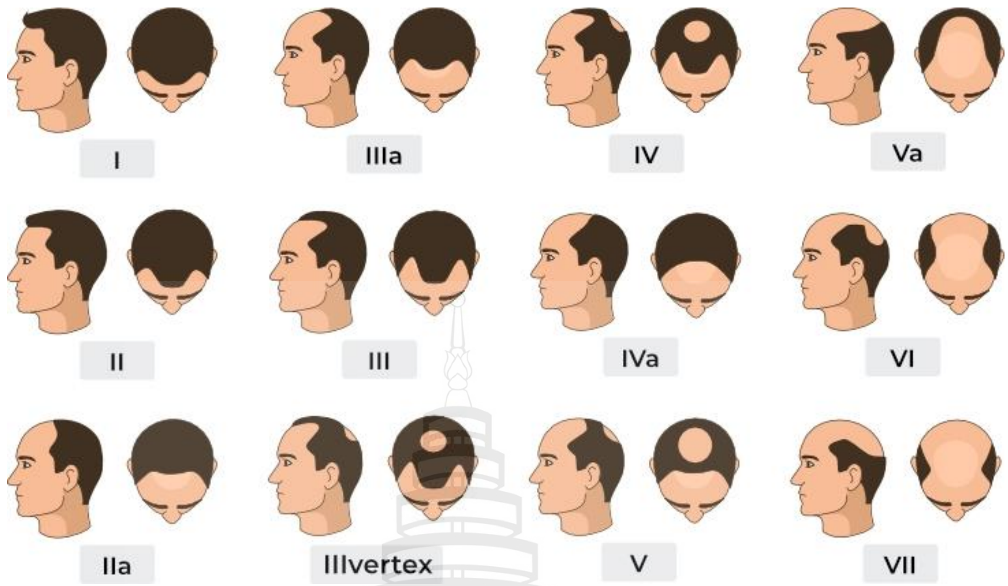

Figure 2.2 Hamilton Norwood classification of androgenetic alopecia

2.2.2.2 Female pattern, Ludwig type

It is the most commonly found type in women. Normally, there is diffuse hair thinning in the centroparietal area preserving the frontal hairline. There are 2 scales describing this pattern, the 3-point Ludwig scale, and the 5-point Sinclair scale (Kang, 2019).

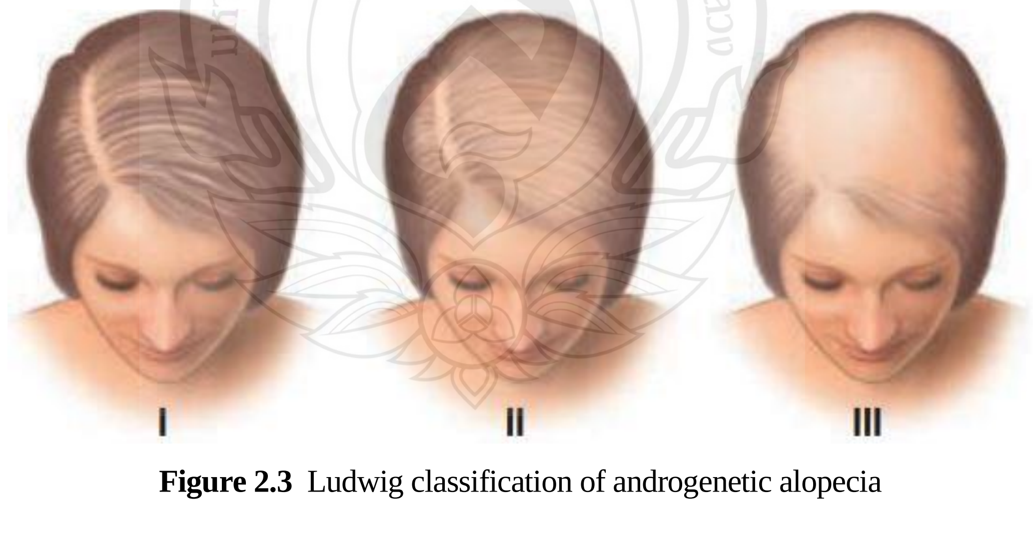

Figure 2.3 Ludwig classification of androgenetic alopecia

Figure 2.4 Sinclair classification of androgenetic alopecia

2.2.2.3 Olsen classification (Christmas tree pattern)

The Christmas tree pattern is the same as the Ludwig pattern, the only difference is involving the frontal hairline. It is also frequently found in women(Kang, 2019).

Figure 2.5 Olsen classification of androgenetic alopecia

2.2.3 Treatment

Treatment of the alopecia is a sophisticated process that involves many growth factors, cytokines, and hormones (Truong & Jeong, 2021). Among all the treatment options, 1mg of oral Finasteride with 2-5% topical minoxidil solution is the only US Food and Drug Administration (FDA)-approved (Kelly et al., 2016).

2.2.3.1 Minoxidil

The first and the only topical drug approved by the FDA to treat Androgenetic alopecia is 2-5% minoxidil. The exact mechanism is still unknown. Some studies state that minoxidil increases the vascular endothelial growth factor (VEGF), promoting hair growth, hair shaft thickening, and hair density. Due to its anti-apoptotic action, it can also maintain the anagen phase for a certain period of time. There is a theory that suggests that minoxidil can also increase the prostaglandin E2 (PGE2) synthesis through the action on prostaglandin endoperoxide synthase-1. It can also lead to hair growth. Important adverse effects of minoxidil are contact dermatitis due to propylene glycol and facial hypertrichosis. But hypertrichosis is just a transient side effect that can relieve 1-3 months after cessation of the application. To prevent contact dermatitis, the foam formulation can be an alternative option. Moreover, at the start of the application, hair shedding is transiently increased (Kelly et al., 2016).

2.2.3.2 Finasteride

Finasteride can decrease the formation of dihydrotestosterone (DHT) by inhibiting the type 2 5a-reductase enzyme, which is mainly responsible for hair follicle miniaturization in androgenetic alopecia. Better responses are seen in young patients with vertex/mid-scalp areas. Finasteride treatment should be continued for a lifetime because returning to the pre-treatment stage is immediately followed within 1year when the drug is stopped. Finasteride should not be used in liver disease and pregnancy. The sexual side effects of finasteride comprise of decreased libido, ejaculated sperm volume, and erectile dysfunction (Kelly et al., 2016).

2.2.3.3 Ketoconazole

Ketoconazole is a drug mainly used as an antifungal treatment. In addition, Ketoconazole has anti-androgenic properties because it can influence steroidogenesis. To decrease scalp DHT levels, it can be used in combination with oral finasteride 1 mg. (Kelly et al., 2016)

2.2.3.4 Hair transplantation

Hair transplantation is the best choice treatment for patients who are older than 25 years with stabilized hair loss. The hair follicles from androgen-insensitive areas are transferred and transplanted into an androgen-dependent scalp. Nowadays, hair transplantation becoming more and more popular in androgenetic alopecia. However, there is no exact guideline for techniques and patient selection. Also, it depends on the surgeons' abilities and the patient individual characteristics. Follicular unit transplantation is the gold standard technique that leads to a more natural look and provides better outcomes. The complication of hair transplantation is not usually occurred, but infection, pain, and failure of the transplanted hair to grow may be found (Kelly et al., 2016).

2.2.3.5 Laser therapy

Many different types of devices such as combs, hoods, and helmets using the low-level light therapy (LLLT) technique are now abundantly found in the market. The exact mechanism is still unclear. However, due to the ability of the light to activate dormant hair follicles, increase blood flow, and production of growth factors and adenosine triphosphate that stimulate anagen hair (Kelly et al., 2016).

2.2.3.6 Platelet-rich Plasma injection

PRP is rich in b-catenin (which induces differentiation of bulge stem cells), fibroblast growth factor 7 (that prolongs the anagen phase), and B-cell lymphoma protein (Bcl)-2 (which is anti-apoptotic). Normally, pain, redness and pinpoint bleeding can occur. However, there is no exact protocol and information for administration such as optimal dose and frequency of injection (Kelly et al., 2016).

2.2.3.7 Scalp micro-needling

The possible mechanisms of action of Scalp Microneedling in androgenetic alopecia may be due to platelet-derived growth factor (PDGF) that release from the activation of platelet and regeneration of skin wound, activation of follicle stem cells from wound healing, and expression of genes that are associated with hair growth such as VEGF, b-catenin, Wnt3a, and Wnt10b (Kelly et al., 2016).

2.2.3.8 Herbal preparations

Since topical minoxidil and finasteride have limitations despite of effectiveness, researchers are currently focused on herbal ingredients for alternative treatment of alopecia. Also, they are much cheaper and widely used in traditional medicine. In addition, herbal extracts have greater advantages because of their effectiveness with fewer adverse reactions (Zgonc Škulj et al., 2020).

2.3 Korean Red Ginseng

2.3.1 General Information

Firstly, raw ginseng can be converted to white ginseng and red ginseng to enhance the properties and the effect. White ginseng is able to turn into black ginseng through the steaming process (Lee et al., 2011). Korean Red ginseng, *Panax ginseng*

C. A. Meyer is under the class Araliacae and has been used throughout the world as traditional medicine. Numerous research papers proved that P. ginseng has many ingredients called ginsenosides that affect mainly on the nervous system and immune systems (Liu et al., 2020).

Figure 2.6 Korean red ginseng (*Panax ginseng* C. A. Meyer)

Ginseng is comprised of 3 parts; the rhizome and the main and fibrous root. The rhizome contains more genocides than the main root (Murata et al., 2012). Korean red ginseng can delay the process of photoaging through its anti-inflammatory and anti-oxidant action in turn destroying free radicals like nitric oxide. In addition, red ginseng has so many protective actions from free radical damage to internal organs like the liver, brain renal, blood vessels, and so on (Liu et al., 2020).In many Asian countries, large numbers of traditional herbs and ways have been used for the prevention of hair loss. Among the Korean red ginseng is the most effective and safest one not only for hair loss but also for new growth (Oh & Son, 2012).

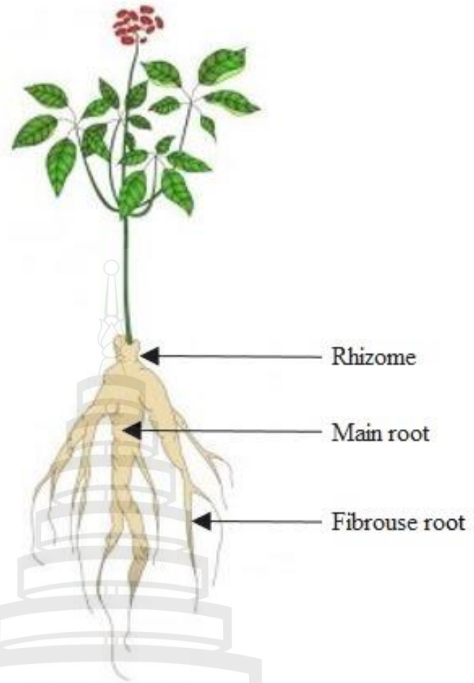

Figure 2.7 Structure of *Panax ginseng* C. A. Meyer

2.3.2 Chemical Constituents of Korean Red Ginseng

More than 200 substances can be processed from Korean Red ginseng. These are ginsenosides, amino acids, Ginseng polysaccharides, polyacetylenes, and volatile oils. Unlike other constituents, ginsenosides are the most abundant and characteristic components of Korean Red ginseng (Liu et al., 2020).These ginsenosides are further subdivided into Ro, Rb1, Rb2, Rc, Rd, Re, Rf, Rg1, Rg3 (Murata et al., 2012).

2.3.3 Biological Properties of Korean Red Ginseng

2.3.3.1 Effect on Androgenetic Alopecia

The extract from Korean red ginseng contains the most powerful ginsenosides that can inhibit the 5α reductase enzyme, which is one of the most important pathogenesis of androgenetic alopecia. These ginsenosides are present four-six times more in rhizome than the main root of Korean Red ginseng. Among these ginsenosides, ginsenoside Ro and Rg3 play a pivotal role in opposing the action of the 5α reductase enzyme. Again, compared to the action of ginsenoside Ro, Rg3 has more powerful and potent inhibitory action against the enzyme 5α reductase enzyme. Murata et al study has already proved about the topical application of Korean Red ginseng successfully suppress the action of testosterone and re-grows the hair on shaved and bald skin in mice. Moreover, Oh and Son (2012) study published that the hair growth effect of Korean red ginseng is contributed to the ginsenoside Rb1 also (Oh & Son, 2012).

Kim et al. reported Korean Red ginseng can recover hair loss by promoting the proliferation and downregulating the apoptosis of hair follicles (Oh & Son, 2012). Any pathways that activate the apoptosis of hair cells can result in hair loss. Anti-apoptotic gene Bcl2 and pro-apoptotic BAX are the key regulatory gene of the apoptosis process. Korean Red ginseng has the property that can enhance the action of Bcl2 and suppress BAX expression prolonging the hair dermal papilla cell survival. This type of action can also be observed in Minoxidil-treated patients.(Truong & Jeong, 2021).

Over and above that, ginsenoside Re can suppress the genes that are related to the TGF β pathway which influences the transition phase of hair growth into catagen (Choi, 2018). In addition, hair follicle development and proliferation can be mainly enhanced by Wnt/ β-catenin signaling pathways. Korean Red ginseng can upregulate the β-catenin protein in dermal papilla cells and promote hair follicle expansion. The ginsenoside Rb1 also takes part in dermal papilla cell proliferation by activation of ERK and Akt pathways. Regulation of apoptosis and antioxidant properties of Korean Red ginseng may also involve in hair development. Local application of its extract induces the formation of growth factors; VEGF and IGF-1. Normally, oxidative free radical promotes hair aging by inhibiting the anagen phase hence reducing new hair growth. The antioxidant properties of Red Ginseng are another important clue for hair regeneration. (Truong & Jeong, 2021).

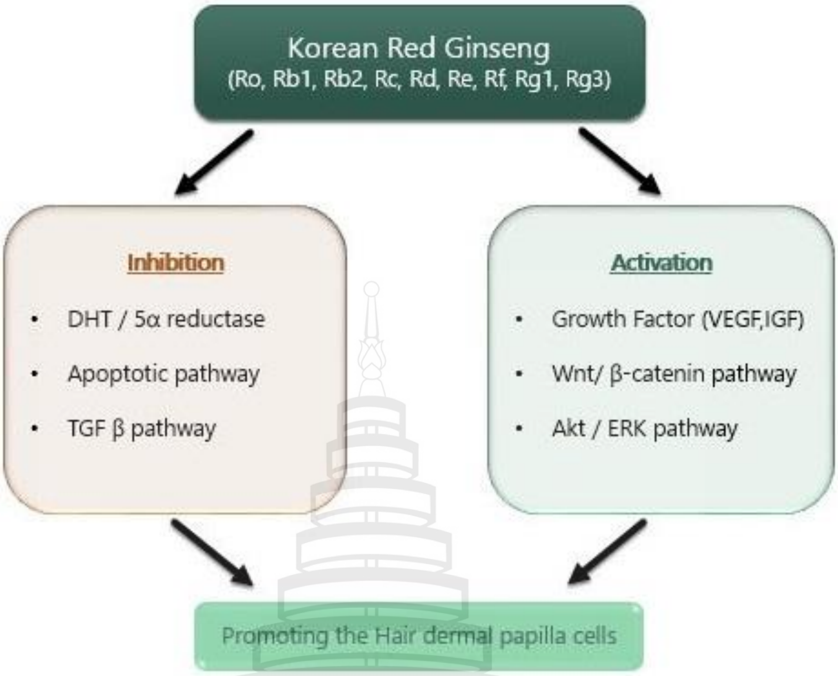

Figure 2.8 Effect of Korean red ginseng on hair growth

2.3.3.2 Anti-aging effect

Ginseng polysaccharides (GPS) and their ginsenosides get rid of the free radicals by increasing the total glutathione and superoxide dismutase (SOD) and reducing the matrix metalloproteinases (MMP-1 and MMP-2).In this way, ginseng can protect the skin damage from UVB radiation. It can also be used to prevent wrinkles and atopic dermatitis (Liu et al., 2020).

2.3.3.3 Anti-inflammatory effect

Ginsenosides Rb1, Rb2, Rd, Re, Rg1, and Rg3 reduce the synthesis of inflammatory cytokines and take part in inflammatory signaling pathways (eg NF-κB and activin 1) (Liu et al., 2020).

2.3.3.4 Cardioprotective effects

Ginsenoside Re decreases the risk of getting ischemic reperfusion (IR) injury by activating the cardiac K+ channel via nitric oxide (Liu et al., 2020).

2.3.3.5 Protection against cerebrovascular injury

Ginsenosides Rd, Rb1, and Rg1 are the most important ingredients for the prevention and treatment of cerebrovascular accidents. Ginsenoside Rd can suppress the microglial proteosome in turn reduces the ongoing inflammation. This Rd can improve patient outcomes with ischemic stroke with favorable safety (Liu et al., 2020).

2.3.3.6 Neuroprotective effect

Ginsenoside Rg1 acts on the GSK-3β/tau and glucocorticoid receptor-ERK signaling pathways preventing Aβ deposition. Moreover, the neuroprotective effect of Korean Red ginseng is related to Rg1 which is mediated through the PI3K/Akt/GSK-3β pathway. Ginsenoside Rg1 can save nerve damage by reducing Aβ and mitochondrial proteins which control the apoptosis signaling pathway (Liu et al., 2020).

2.3.3.7 Antitumor effect

Rg3, GPS, and pectin can be considered as important ones in antitumor effects. Ginsenoside Rg3 decreases colorectal cancer cell growth and modifies the tumor's microenvironment by inhibiting angiogenesis and promoting immunity (Liu et al., 2020).

2.3.3.8 Diabetes mellitus treatment

The ginsenosides enhance insulin synthesis and reduce gluconeogenesis (Liu et al., 2020).

2.3.4 Toxicity & Safety

The toxicity and safety of Korean Red ginseng are not well established yet. Although the toxicity of ginseng is infrequent, adverse reactions such as restlessness, insomnia, hypertension, and GI disturbances are seen in chronic long-standing oral administration of ginseng extract. Misused ginseng extract in large doses (around 15g per day) can lead to confusion and depression. Due to the estrogen-like properties of ginseng, long-term ingestion can also result ginseng – induced gynecomastia (Kitts & Hu, 2000; Paik & Lee, 2015). In addition, some studies reported that exposure to ginseng components can result allergic and anaphylactic reactions (Paik & Lee, 2015). However, compared to other ginsengs, Korean Red ginseng becomes less toxic after being processed from raw ginseng (Yang et al., 2014). Over and above that, no exact data is available for the topical preparation of Korean Red ginseng. Hence, to clarify the effectiveness and safety of Korean Red ginseng extract as hair lotion for androgenetic treatment, this research was conducted.

2.4 Vitamin B5

2.4.1 General Information

Vitamin B5 is commonly used as a medication and dietary supplement for nutrient deficiencies. (Bregnbak et al., 2016) Dexpanthenol (D-panthenol) is a derivative of vitamin B5 (pantothenic acid) which is oxidized inside the peripheral tissue (Shin et al., 2021). Due to the moisturizing and conditioning action of D-panthenol, it is widely used in the cosmetic and pharmaceutical industries (Bregnbak et al., 2016) and is popular in the market as supplements and topical cream. Many of the previous research studies of D-panthenol are mainly emphasized on skin regeneration and wound healing. Very few papers were done on anti-hair loss treatment, although it is widely used for hair and scalp care products (Shin et al., 2021).

Figure 2.9 Vitamin B5

When the skin is exposed to UV radiation, the glutathione content which prevents lipid peroxidation is dramatically reduced resulting in cell apoptosis. This effect is reversed by D-panthenol indicating its strong anti-oxidant property. It also increases co-enzyme A and thus promotes ATP synthesis within the cell. Therefore, Dexpanthenol can promote cellular repair mechanisms (Kutlu, 2020).

2.4.2 Biological Properties of Vitamin B5 on Hair

D-panthenol can increase the level of Ki67 in human dermal papilla cells which is the marker of cellular proliferation indicating that D-panthenol can speed up cell viability. In aging and dead hair follicles, apoptosis markers (Caspase3/9) and cell senescence (p21/p16) are significantly raised in expression.D panthenol can effectively reduce these markers in hair follicles. Moreover, D panthenol can prolong the anagen phase which is responsible for hair length and density by stimulating alkaline phosphatase, β-catenin, and versican. For effective anti-hair loss treatment, it is essential both to maintain the anagen phase and inhibit the catagen phase. TGF-β1 in bald dermal papilla cells are well known for stimulation of hair follicles to enter the catagen phase. D-panthenol can effectively suppress TGF-β1 expressions not only in mRNA but also in protein levels (Shin et al., 2021).

When vascular endothelial growth factor bind to its receptor in the dermal papilla and outer root sheath, it can stimulate cell proliferation which is crucial for hair growth. On the other hand, VEGF can prolong the anagen phase and promote angiogenesis. This vascular endothelial growth factor expression is found to be increased by D-panthenol (Shin et al., 2021).

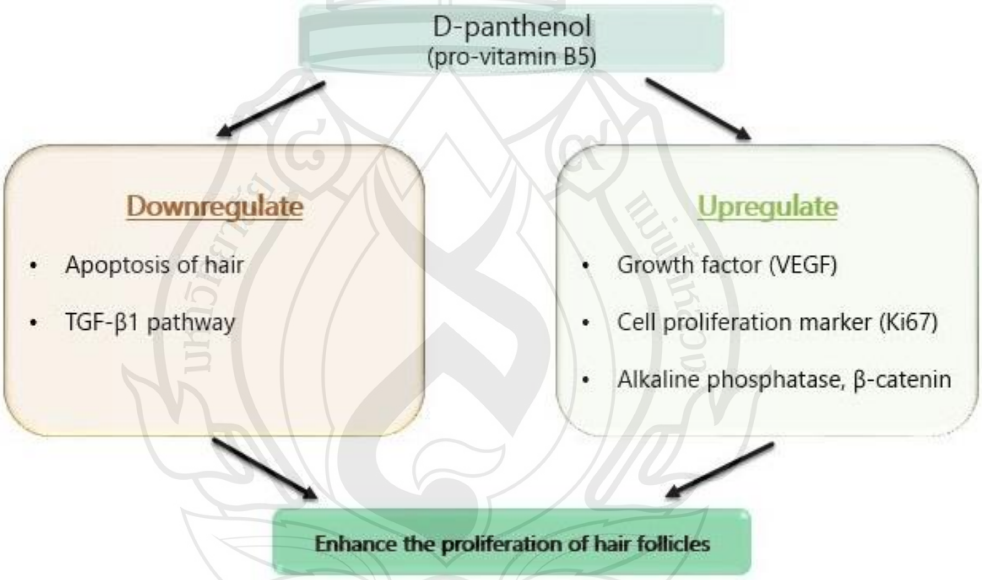

Figure 2.10 Effect of D-panthenol on hair proliferation

2.4.3 Toxicity & Safety of Vitamin B5

In general, it is considered to be safe to take vitamin B5 since it is a water-soluble vitamin. The toxicity is seldom seen. However, some adverse reactions may arise with the oral administration of this drug. These adverse effects include joint and muscle pain, headache, dizziness, nausea, abdominal pain, constipation, hypersensitivity reaction, and increase in the serum level of creatine phosphokinase CPK and alanine transaminase ALT (Sanvictores & Chauhan, n.d.). As for D-panthenol, a pro-form of vitamin B5, there are some reports that after using cosmetics or medicaments containing D-panthenol resulted allergic contact dermatitis, although it is uncommon (Chin et al., 2013; Bregnbak et al., 2016)

CHAPTER 3

RESEARCH METHODOLOGY

3.1 Study Design

Quasi-Experimental, Clinical Study

3.2 Study Population

3.2.1 Sample

Twelve healthy male patients of age between 25-45 years and Hamilton Norwood type of Androgenetic alopecia ranging from I to III.

3.2.2 Sample Size Determination

A similar article for Efficacy and Safety of Platelet Rich Plasma Therapy in Male Androgenetic Alopecia was used for the sample size population (Sultana & Paul, 2020). The hair count (per cm^2) showed 15.56 ± 1.88 at baseline to 17.62 ± 2.07 in the 12^{th} week.

From the formula, $\alpha = 0.05$ (two-tailed) $Z_{0.025} = 1.96$, $Z_{0.10} = 1.28$

$n_1 = 27 \quad n_2 = 27$

$\sigma_1 = 1.88 \quad \sigma_2 = 2.07$

$S^2_p = [(n1 - 1)\ S^2_1 + (n2 - 1)\ S^2_2] / n_1 + n_2 - 2$

S^2_p (pooled variance) = 3.91

$$n = (Z_{\alpha/2} + Z_{\beta})^2\, \sigma^2 / (\mu_1 - \mu_2)^2$$

$$= (1.96 + 1.28)^2\, 3.91 / 4.24 = 9.68 \text{ or } 10 \text{ subjects}$$

Note

n = sample size

σ = Standard deviation

The estimated dropout rate is 20%. Thus 12 subjects (n=12 recruited)

3.2.3 Inclusion Criteria

Male volunteer of age between 25-45 years with androgenetic alopecia Hamilton Norwood type ranging from I to III

3.2.3.1 Patients who are not currently receiving any hair treatment.

3.2.3.2 Patients who needed treatment for androgenetic alopecia.

3.2.3.3 Patients who are willing to participate in the treatment and come to every follow-up for 3 months.

3.2.4 Exclusion Criteria

3.2.4.1 Patients who are currently receiving treatment with Minoxidil or finasteride.

3.2.4.2 Patients who have a history of contact dermatitis.

3.2.4.3 Patients who have an allergic history of Vitamin B5 and components of Korean Red Ginseng.

3.2.4.4 Patients who are having unrealistic expectations.

3.2.4.5 Patients with a history of diabetes, hypertension, and other systemic diseases

3.2.4.6 Current cigarette smoking, heavy drinking, and drug abuse

3.2.4.7 Patients who had been enrolled in other research studies within a period of 3 months.

3.2.5 Discontinuation Criteria

3.2.5.1 Patients who want to quit the treatment due to any reasons.

3.2.5.2 If any exclusion criteria are shown.

3.2.5.3 A patient who develops skin irritation, allergic reaction, contact dermatitis, and other adverse effects after receiving the treatment.

3.2.5.4 Failure in a follow-up visit

3.3 Study Location

Mae Fah Luang University Hospital, Bangkok.

3.4 Research Instrument

3.4.1 Patient record form

3.4.2 Informed consent form

3.4.3 Clinical evaluation record form

3.4.4 Adverse effect record form

3.4.5 Questionnaires and satisfaction assessment form

3.4.6 Patch Test

3.4.7 Template marker and Cling sheath

3.4.8 Trichoscope for hair count assessment.

3.4.9 Korean Red ginseng and VitaminB5 containing Hair lotion

3.5 Variables of the Study

3.5.1 Independent Variable

Hair lotion containing Korean Red Ginseng and Vitamin B5

3.5.2 Dependent Variable

Hair count assessment by trichoscope

1. Modified Global Photographic Assessment Score
2. Participant Satisfaction Score
3. Adverse effects

3.6 Study Procedures

3.6.1 Preparation of Research Subjects

3.6.1.1 12 volunteers were enrolled according to inclusion and exclusion criteria.

3.6.1.2 The researcher explained in detail about the purpose and treatment procedure including the benefit and possible side effects after treatment.

3.6.1.3 The researcher took a written informed consent form from each volunteer.

3.6.1.4 General information about the volunteers including personal profiles, previous medical history, and history that are related to the research study.

3.6.1.5 Before applying the hair lotion to the scalp, a patch test for Korean Red Ginseng and Vitamin B5 was done to each volunteer. The test was carried out on the dry, forearm skin of volunteers under a waterproof patch for 24hours. Volunteers were informed not to be exposed to heavy sunlight and to avoid excessive sweating during the test. The tested skin area is re-examined for any reaction in 48 & 96hours. The scoring system is graded by the international contact dermatitis research group system which can be seen below;

(-) = no reaction

+ ? = any doubtful reaction (mild redness without infiltration)

+ = weak positive reaction (redness and skin is slightly thickened)

+ += strong positive reaction (skin is red and swollen with small blister)

+ + + = extreme positive reaction (intense red swelling with coalesced spreading reaction or large blisters.

N T = Allergen is not tested

I R = Irritant reaction.

Volunteers with positive patch test starting from score + + were excluded

3.6.1.6 Hair count (Hair Density) assessment will be elucidated by using Aramo® SG Skin and Hair Diagnosis System.

3.6.1.7 Modified Global Photographic Assessment Score was done by using the digital camera for the baseline, photographic images were taken in 2 positions of the head; Vertex position and Forehead position.

Figure 3.1 Two different positions of hair assessment for modified global photographic assessment score

3.6.1.8 Instruction for application of hair lotion

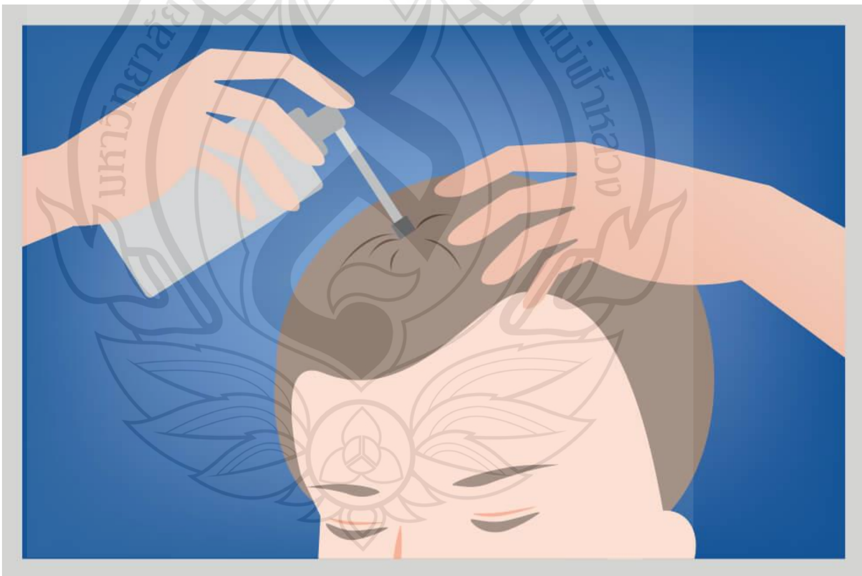

Figure 3.2 Instruction for applying hair lotion

1. Hair lotion is applied to the baldness areas of the scalp twice a day: (in the morning and at night), 2puff to the affected area

2. Hair lotion should only be applied 2 hours after washing and drying the hair.

3. After the application of hair lotion, give a gentle massage to the areas of baldness.

4. Avoid activities that cause excessive sweating and use a hair dryer after application.

5. Volunteers should not be taken any other hair treatment during the research period.

6. If any adverse reactions are observed, stopped immediately.

3.6.2 Follow-up

All volunteers are requested for follow-up at 4th, 8th, and 12th week to assess the improvements and adverse reactions.

3.7 Outcome Measurement and Data Collection

3.7.1 Modified Global Photographic Assessment Score

The improvement was evaluated by comparing digital photographs at baseline and 4th, 8th, and 12th weeks by Modified Global Photographic Assessment Score.

1 = Significant disease progression

2 = Moderate disease progression

3 = Slight disease progression

4 = No change is seen

5 = Slight improvement

6 = Moderate improvement

7 = Significant improvement

*Baseline MGPA = 4

*Photographic must be taken in 2 positions; Vertex & forehead.

3.7.2 Subjective Evaluation

Satisfaction will be evaluated by the participant's satisfaction score by using a grading scale at the 4th, 8th, and 12th weeks.

-1 = unsatisfied

0 = indifferent

1 = somewhat satisfied

2 = moderately satisfied

3 = very satisfied

4 = completely satisfied

3.7.3 Objective Evaluation

3.7.3.1 Hair count from the scalp area will be evaluated by using Aramo® SG Skin and Hair Diagnosis System. Measurements were done at baseline, 4th, 8th, and 12th week.

3.7.3.2 The adverse effect will be questioned at the 4th, 8th, and 12th weeks by research questionnaire.

3.8 Research Materials

3.8.1 Aramo® SG Skin and Hair Diagnostic System

Figure 3.3 Aramo® SG skin and hair diagnostic system

Aramo® SG Skin and Hair Diagnostic System is a powerful non-invasive device that can assess not only elasticity, moisture, sebum, spots, wrinkles, and pigmentation of the skin, but also hair density, scalp conditions, and hair loss statements. This device is equipped with a small multifunction camera with a high magnifying lens (1x, 10x, 200x, and 1000x). In addition, it is connected to the computer and the condition of the skin and hair can be visualized immediately.

3.8.2 Hair Lotion Containing Korean Red Ginseng and Vitamin B5

Each plastic bottle of hair lotion contains 30 ml of Korean Red ginseng and D-panthenol (pro-vitamin B5) extracts (1:1 Ratio) which are composed and manufactured by Derma Innovation.Co., Ltd. Hair lotion is made up of serum-type texture with clear color. Ingredients contained in this hair lotion are listed as follows;

1. Major ingredient
   1) Korean Red ginseng extract
   2) D-panthenol extract (pro-vitamin B5)
2. Other:
   1) Water
   2) Butylene glycol
   3) Propanediol
   4) Ethoxydiglycol
   5) Polysorbate 20
   6) Phenoxyethanol
   7) Chlorphenesin
   8) Fragrance
   9) Disodium EDTA
   10) Glycerin
   11) Citric acid

3.9 Data Analysis

3.9.1 Volunteer selection for this research will be filtered by using inclusion and exclusion criteria, and personal profiles are strictly confidential.

3.9.2 The research is conducted in Mae Fah Luang University Dermatology Clinic, and all data will be analyzed by using SPSS 18 software and Microsoft Excel 2010.

3.9.3 General demographic data of participants will be documented by using descriptive statistical analysis including means, medians, modes, ranges, and standard deviations.

3.9.4 The outcome of Participant Satisfaction Scores and Modified Global Photographic Assessment Scores are ordinal (non-parametric) time factors (each follows) with repeated measurement will be tested the difference by McNemar's test.

3.9.5 Compare the mean of hair count from the trichoscope before treatment with each follow-up visit by using repeated measure ANOVA for statistical significance.

3.9.6 Statistical significance was set as a p-value of less than 0.05.

3.10 Ethical Considerations

This research has been performed with Good Clinical Practice (GCP), which is considered as ethical and scientific standard for the design, conduct, recording, and reporting of clinical research involving the participation of human subjects and must be approved by the human research committee of Mae Fah Luang University. The participants will gain assurance that the rights, safety, and well-being of research subjects are respected according to ethical considerations.

The research should be justified on basis of a favorable risk and benefit assessment during the study protocol. Safety, rights, and the well-being of participants is the most important thing to keep in mind, and it takes priority over academic and social benefits. All participants will be informed the standard information on how clinical trials should be conducted before the process of informed consent. All information related to the research will be kept confidential. In addition, the results of the research will not include personal data as well. The researcher will inform possible side effects and feelings during the treatment to relieve the nervousness of the participants.

For the benefits of this study, the participants will receive a new treatment option for androgenetic alopecia with the combination treatment of Korean Red Ginseng and Vitamin B5 hair serum. This is an opportunity to learn how Korean Red Ginseng and D-panthenol (pro-Vitamin B5) affect on regeneration of hair follicles and prevention of hair loss leading to the development of medical knowledge that is waiting for researchers to conduct further studies in the future. 0.05.

CHAPTER 4

RESULTS

4.1 General Characteristics of the Sample

The general demographics data for 12 volunteers were analyzed by using descriptive statistical methods.

Table 4.1 Participants' demographic characteristic

Demographic	**n=12**
Male	12
Female	0
Age Groups (years)	
Mean ± SD	30.67 ± 2.5
Range	25-45
Occupation (n)	
Employee	4
Student	7
Teacher	1
Pre-existing disease (n)	
YES	0
NO	12
Current Medication (n)	
YES	0
NO	12
History of allergy (n)	
YES	0
NO	12

Table 4.1 (continued)

Demographic	n=12
Hamilton-Norwood Classification	
Range	Type I – III
Type 1	4
Type II	8
Type III	0

12 of the total participants are all men. The mean age is 30.67 ± 2.5. Among the volunteers, 4 are employees, 7 are students and 1 teacher. 4 participants are classified as Hamilton-Norwood Type 1 alopecia & the rest are Type II. All volunteers denied any medical disease, allergic history, or current medication history.

4.2 Hair Count (Hair Density) Assessment Evaluated by Aramo SG

Table 4.2 Statistical analysis of hair count (hair density) assessment at baseline, week-4, week-8 and week-12

Hair count (hair density)	Mean	SD
Baseline	19.75	1.357
Week-4 After Treatment	20.17	1.697
Week-8 After Treatment	21.25	1.865
Week-12 After Treatment	22.08	2.234
P value	**0.001***	

Note The p-value was obtained through Repeated Measures ANOVA

* Significance was determined at the 0.05 level.

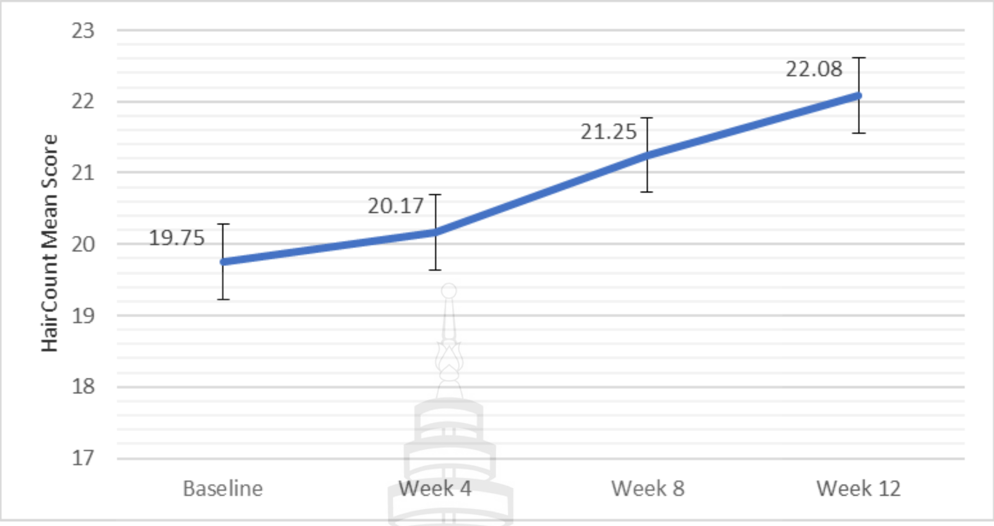

Figure 4.1 A line graph illustrating the progression of hair count (hair density) from baseline through the follow-up visits at week-4, week-8 and week-12

Based on the analysis, the mean hair count (hair density) was 19.75 ± 1.36 at baseline, increasing to 20.17 ± 1.70 at the Week-4, 21.25 ± 1.87 at the Week-8, and 22.08 ± 2.23 at the Week-12. A statistically significant increase in hair count was observed across all follow-up visits at the 0.05 level ($p < 0.001$).

Table 4.3 Multiple comparisons of hair count (hair density) assessment at baseline, follow-up visits week-4, week-8 and week-12

Time	Pair Comparison	Mean difference	P value
Baseline	Week-4	-0.417	1.000
	Week-8	-1.500	0.025*
	Week-12	-2.333	0.004*
Week-4	Baseline	0.417	1.000
	Week-8	-1.083	0.001*
	Week-12	-1.917	0.001*
Week-8	Baseline	1.500	0.025*
	Week-4	1.083	0.001*
	Week-12	-0.833	0.012*

Table 4.3 (continued)

Time	Pair Comparison	Mean difference	P value
Week-12	Baseline	2.333	0.004*
	Week-4	1.917	0.001*
	Week-8	0.833	0.012*

Note Multiple comparisons were analyzed using Bonferroni method.
* The difference in means is considered statistically significant at the 0.05 level.

The multiple comparison results from Table 4.3 show that the hair count (hair density) at baseline was significantly greater than at the Week-8 (-1.500, $p = 0.025$) and the Week-12 (-2.333, $p = 0.004$), demonstrating significance at the 0.05 threshold ($p < 0.05$). Likewise, hair count at Week-4 was considerably higher than at the Week-8 (-1.083, $p = 0.001$) and the Week-12 (-1.917, $p = 0.001$). A notable decline was also observed between the 8th and Week-12 (-0.833, $p = 0.012$).

4.3 Modified Global Photographic Assessment Score (MGPA Score)

MGPA score is classified as:

- Major disease progression = 1
- Moderate disease progression = 2
- Minor disease progression = 3
- No change = 4
- Minimal improvement = 5
- Moderate improvement = 6
- Major improvement = 7

Table 4.4 Evaluation of MGPA score on week-4, week-8 and week-12

	MGPA, n (%)						
	1	2	3	4	5	6	7
Week-4	-	-	-	12 (100.0)	-	-	-
Week-8	-	-	-	9 (75.0)	3 (25.0)	-	-
Week-12	-	-	1 (8.3)	3 (25.0)	7 (58.5)	1 (8.3)	-

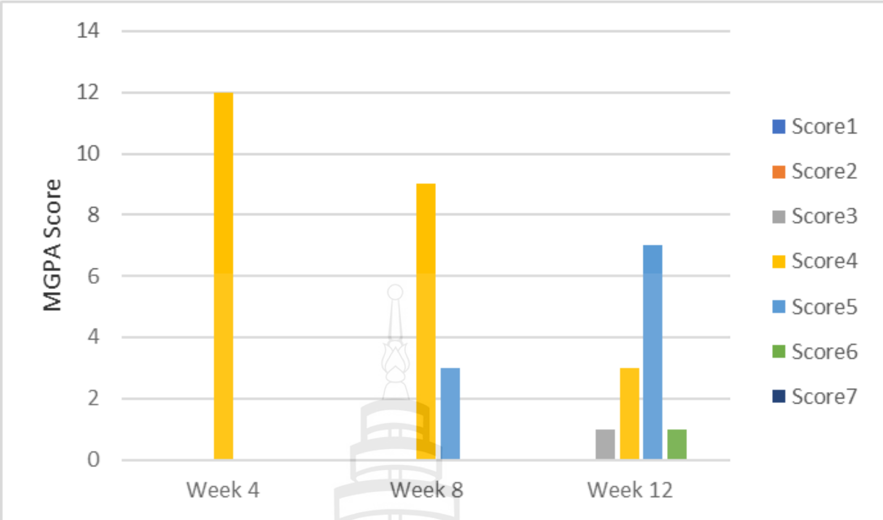

Figure 4.2 Bar graph showing MGPA score on week-4, week-8 and week-12

Table 4.5 Statistical analysis of MGPA score

MGPA Score	Mean	SD
Week-4	4.00	0.00
Week-8	4.25	0.452
Week-12	4.67	0.778
P-value	**0.012***	

Note * Statistically significant at the 0.05 level (P<0.05)

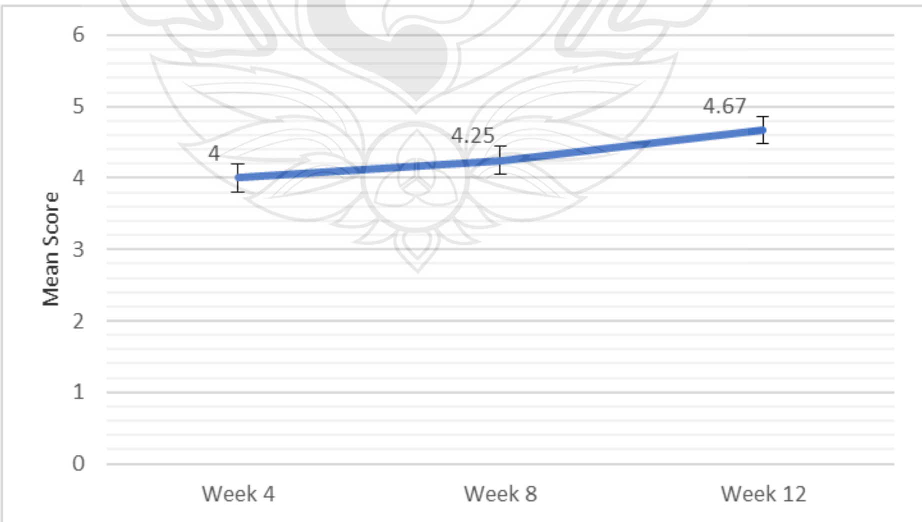

Figure 4.3 Linear graph showing MGPA score on week-4, week-8week-12

Table 4.4 and Figure 4.2 show that all participants had an MGPA score of 4 at the Week-4, with slight improvements observed in some participants by Week-8 and Week-12. By the Week-12, most participants showed improvement, with scores ranging from 3 to 6. Table 4.5 indicates a steady increase in the mean MGPA score over time, which was statistically significant ($p = 0.012$), reflecting gradual improvement in participants’ conditions.

Table 4.6 Multiple comparisons of MGPA between week-4, week-8 and week-12

Time	Pair comparison	P-value
Week-4	Week-8	0.083
Week-4	Week-12	0.021*
Week-8	Week-12	0.059

Note * Statistically significant at the 0.05 level

Based on the multiple comparison results from Table 4.6, the MGPA score at Week-12 was significantly greater than at Week-4 ($p = 0.021$), showing statistical significance at the 0.05 level ($p < 0.05$). However, the differences between Week-4 and Week-8 ($p = 0.083$) and between Week-8 and Week-12 ($p = 0.059$) were not statistically significant.

4.4 Patient Satisfaction Score

Patient satisfaction score is graded as

Unsatisfied = - 1
Indifferent = 0
Slight satisfied = 1
Moderately satisfied = 2
Very satisfied = 3
Completely satisfied = 4

Table 4.7 Assessment of patient satisfaction score on week-4, week-8, week-12

	Patients' Satisfaction, n (%)					
	-1	**0**	**1**	**2**	**3**	**4**
Week-4	-	5 (41.5)	7 (58.5)	-	-	-
Week-8	-	2 (16.6)	10 (83.4)	-	-	-
Week-12	-	1 (8.3)	8 (66.7)	3 (25.0)	-	-

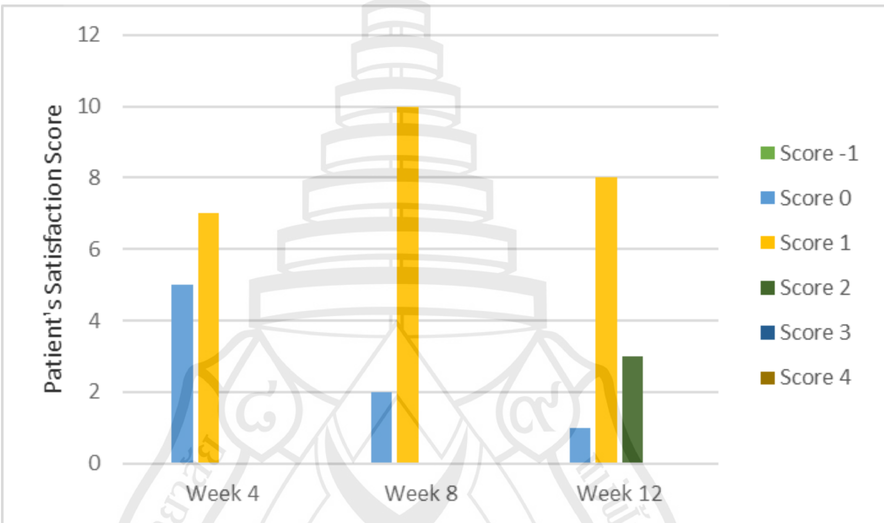

Figure 4.4 Bar graph showing patient satisfaction score on week-4, week-8, week-12

Table 4.8 Statistical analysis of patient satisfaction score

Patient Satisfaction Score	**Mean**	**SD**
Week-4	0.58	0.515
Week-8	0.83	0.389
Week-12	1.17	0.577
P value	**0.005***	

Note * Statistically significant at the 0.05 level

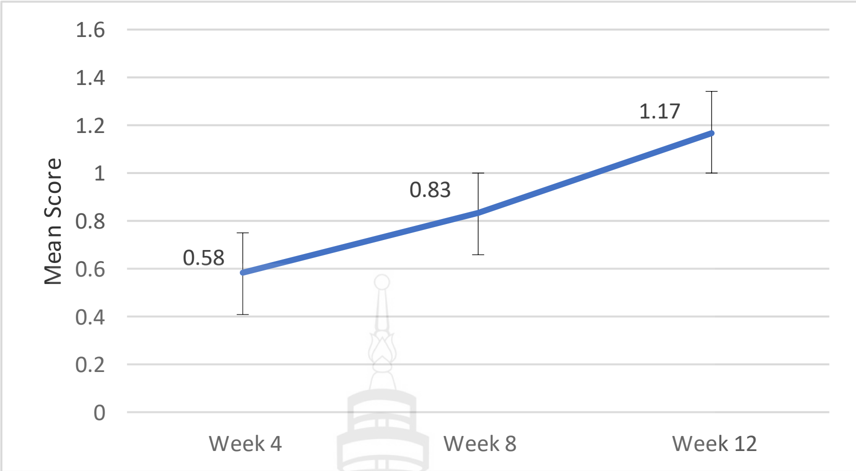

Figure 4.5 Line plot showing patient satisfaction score on week-4, week-8, week-12

According to Table 4.7 and Figure 4.4, patient satisfaction improved over time, with 58.5% of participants somewhat satisfied at the Week-4, 83.4% at the Week-8, and 66.7% at the Week-12, where 25% also reported moderate satisfaction. As shown in Table 4.8, the mean satisfaction score increased from 0.58 at the Week-4 to 1.17 at the Week-12, with the improvement being statistically significant ($p = 0.005$).

Table 4.9 Multiple comparisons of patient satisfaction score between week-4, week-8, week-12

Time	Pair comparison	P-value
Week-4	Week-8	0.083
Week-4	Week-12	0.008*
Week-8	Week-12	0.046*

Note Significance values have been adjusted by the Bonferroni correction for multiple tests.

* Statistically significant at the 0.05 level

The results from the multiple comparisons in Table 4.9 indicate that the patient satisfaction score at Week-12 was significantly higher compared to both Week-4 and Week-8. Additionally, the score at Week-8 exceeded that of Week-4, with all observed differences being statistically significant at the 0.05 threshold ($p < 0.05$).

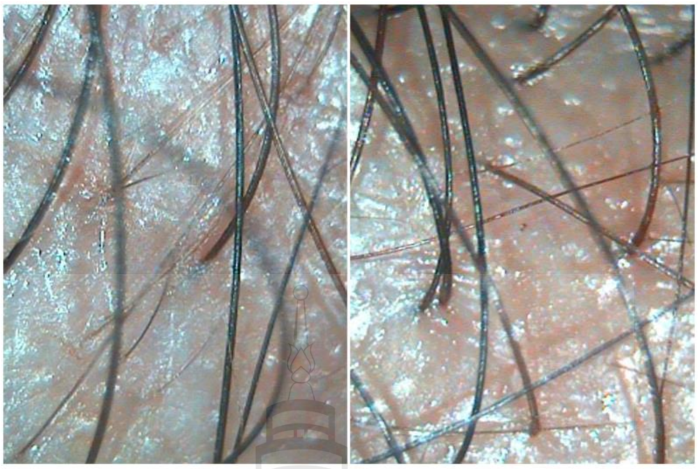

Figure 4.6 Hair count (hair density) assessment between before treatment and week-12 after treatment

4.5 Adverse Effects

During the entire research process, no adverse effects were observed in any of the subjects.

CHAPTER 5

DISCUSSION, CONCLUSION AND SUGGESTION

5.1 Discussion

Androgenetic alopecia (AGA) is the most common form of hair loss, affecting both men and women worldwide. It is characterized by progressive miniaturization of hair follicles due to the effects of dihydrotestosterone (DHT) on androgen-sensitive follicles (Kaufman, 2002). While pharmacological treatments such as minoxidil and finasteride have been widely used, their side effects and long-term safety concerns have prompted interest in natural alternatives. Korean Red Ginseng (KRG) has been extensively studied for its potential role in hair regrowth. KRG contains active ginsenosides, which are believed to stimulate hair follicle proliferation, reduce inflammation, and improve scalp circulation (Lee et al., 2017). Additionally, Vitamin B5, or pantothenic acid, is known to strengthen hair follicles by improving keratin synthesis, which is essential for hair structure and growth (Park et al., 2019). The combination of these two ingredients is hypothesized to provide a synergistic effect in managing AGA

The findings of this study support the efficacy of Korean Red Ginseng and Vitamin B5 hair lotion in improving hair density among individuals with AGA. The mean hair count showed a progressive increase from 19.75 ± 1.35 at baseline to 22.08 ± 2.23 at the 12th week, with statistical significance ($p<0.001$). These results suggest that the combination treatment can stimulate hair follicle regeneration and slow down AGA-related hair loss.

Furthermore, improvements in hair condition were observed through the Modified Global Photographic Assessment (MGPA) scores, which increased significantly over time. At the 4th week, all participants had an MGPA score of 4 (no change), but by the 12th week, scores ranged from 3 to 6, indicating noticeable improvement in hair density and scalp coverage. Statistical analysis confirmed a significant difference in MGPA scores between the 4th and 12th weeks ($p = 0.021$), demonstrating the progressive effectiveness of the treatment.

Patient satisfaction levels also reflected the positive impact of the treatment. At the 4th week, 58.5% of participants were somewhat satisfied, and by the 12th week, 66.7% were very satisfied, while 25% reported moderate satisfaction. The overall increase in patient satisfaction was statistically significant ($p = 0.005$), suggesting that the combination treatment is well-received and appreciated for its visible improvements in hair growth.

Importantly, no adverse effects were reported throughout the study, confirming the safety profile of the combination treatment. Given these findings, Korean Red Ginseng and Vitamin B5 hair lotion may serve as an effective, natural alternative for managing AGA, especially for individuals seeking non-pharmaceutical interventions.

5.2 Conclusion

The results of this study demonstrate that the combination of Korean Red Ginseng and Vitamin B5 hair lotion is effective in increasing hair density and improving scalp coverage in individuals with androgenetic alopecia. The statistically significant improvements in hair count, MGPA scores, and patient satisfaction levels indicate that this treatment may offer a viable, safe alternative to conventional AGA treatments. With no reported adverse effects, the findings suggest that this combination therapy is both effective and well-tolerated.

5.3 Limitation

Despite the promising results, certain limitations must be acknowledged. The study was conducted on a small sample size consisting exclusively of male participants, which may limit the generalizability of the findings. Additionally, the follow-up period was limited to 12 weeks, making it unclear how long the effects of the treatment persist beyond this timeframe. Lifestyle factors such as diet, stress, sleep quality, and smoking, which may influence hair growth, were not fully controlled. Further research is needed to address these limitations.

5.4 Recommendation

To further validate the efficacy of Korean Red Ginseng and Vitamin B5 in the treatment of androgenetic alopecia, future studies should focus on expanding the sample size to include a more diverse population, incorporating both male and female participants with varying degrees of AGA. Additionally, extending the study duration beyond 12 weeks would help determine the long-term sustainability of the treatment's effects. Comparative studies analyzing the combination treatment alongside standard AGA therapies, such as minoxidil or finasteride, would provide valuable insights into its relative effectiveness. Furthermore, exploring additional benefits, such as improvements in scalp hydration, hair texture, and overall scalp health, could broaden its potential applications in dermatology. Addressing these areas in future research will help establish Korean Red Ginseng and Vitamin B5 hair lotion as a scientifically backed, reliable treatment for androgenetic alopecia.

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APPENDIX A

INFORMED CONSENT FORM

หนังสือแสดงเจตนายินยอมเข้าร่วมในโครงการวิจัย สำหรับอาสาสมัคร

(Informed Consent)

ชื่อโครงการวิจัย

Effectiveness of The Combination Treatment of Korean Red Ginseng and VitaminB5 in Androgenetic Alopecia

การศึกษาประสิทธิผลของ โสมแดงเกาหลีร่วมกับวิตามินบี **5** ในการรักษาโรคผมร่วงจากกรรมพันธุ์

ข้าพเจ้า นาย/นาง/นางสาว.. ที่อยู่..

ได้อ่านรายละเอียดจากเอกสารชี้แจงข้อมูลแก่อาสาสมัครผู้เข้าร่วมในโครงการวิจัยวิจัย ฉบับวันที่........

ข้าพเจ้าได้รับสำเนาเอกสารชี้แจงข้อมูลแก่อาสาสมัครผู้เข้าร่วมในโครงการวิจัย และสำเนาเอกสารแสดงเจตนายินยอมเข้าร่วมในโครงการวิจัยที่ข้าพเจ้าได้ลงนามและลงวันที่ ทั้งนี้ก่อนที่จะลงนาม ข้าพเจ้าได้รับการอธิบายโดยละเอียดจากผู้วิจัยถึงวัตถุประสงค์ วิธีการวิจัย ความไม่สุขสบายหรือความเสี่ยงที่อาจเกิดขึ้น ประโยชน์ที่คาดว่าจะได้รับจากการวิจัย และทางเลือกอื่น

ข้าพเจ้ามีเวลาและโอกาสเพียงพอในการซักถามข้อสงสัย โดยผู้วิจัยได้ตอบคำถามต่าง ๆ ด้วยความเต็มใจไม่ปิดบังซ่อนเร้นจนข้าพเจ้าเข้าใจเป็นอย่างดีแล้ว

ข้าพเจ้ารับทราบจากผู้วิจัยว่า หากเกิดอันตรายใด ๆ จากการวิจัย ข้าพเจ้าจะได้รับการรักษาพยาบาล ตามที่ระบุในเอกสารชี้แจงข้อมูลแก่อาสาสมัครผู้เข้าร่วมในโครงการวิจัย

ข้าพเจ้ามีสิทธิที่จะถอนตัวออกจากโครงการวิจัยเมื่อใดก็ได้ การถอนตัวนี้ไม่มีผลต่อการรักษาพยาบาลและสิทธิอื่น ๆ ที่ข้าพเจ้าจะพึงได้รับต่อไป

ผู้วิจัยรับรองว่าจะเก็บข้อมูลส่วนตัวของข้าพเจ้าเป็นความลับ การรายงานหรือสรุปผลการวิจัยจะไม่ระบุชื่อนามสกุลของข้าพเจ้า การเปิดเผยข้อมูลเกี่ยวกับตัวข้าพเจ้าต่อหน่วยงานต่างๆ ที่เกี่ยวข้อง จะกระทำด้วยเหตุผลทางวิชาการเท่านั้น

ข้าพเจ้าได้อ่านข้อความข้างต้นและมีความเข้าใจดีทุกประการแล้ว ยินดีเข้าร่วมในการวิจัยด้วยความสมัครใจ จึงได้ลงนามในเอกสารแสดงความยินยอมนี้

.... ลงนามผู้เข้าร่วมในโครงการวิจัย

(...) ชื่อ-สกุล ผู้เข้าร่วมในโครงการวิจัย (ตัวบรรจง)

วันที่ ....เดือน...................................พ.ศ.............................

ข้าพเจ้าได้อธิบายโดยละเอียดถึงวัตถุประสงค์ วิธีการวิจัย ความไม่สุขสบายหรือความเสี่ยงที่อาจเกิดขึ้นประโยชน์ที่คาดว่าจะได้รับจากการวิจัย และทางเลือกอื่น ให้ผู้เข้าร่วมในโครงการวิจัยได้ทราบและมีความเข้าใจดีแล้ว พร้อมทั้งลงนามในเอกสารแสดงเจตนายินยอมด้วยความสมัครใจ

... ลงนามผู้วิจัย

ชื่อ-สกุล ผู้วิจัย (ตัวบรรจง)

... ลงนามพยาน

(...) ชื่อ-สกุล พยาน (ตัวบรรจง)

วันที่ ....เดือน...................................พ.ศ.............................

APPENDIX B

INFORMATION SHEET

1. TITLE

EFFECTIVENESS OF THE COMBINATION TREATMENT OF KOREAN RED GINSENG AND VITAMIN B5 IN ANDROGENETIC ALOPECIA

2. OBJECTIVE

2.1 General Objective

To study the effectiveness and safety of the combination treatment of Korean Red ginseng (*Panax ginseng*) and Vitamin B5 in androgenetic alopecia.

2.2 Specific Objective

2.2.1 Primary Outcome

To compare average mean changes of hair count from baseline to 4th, 8th, 12th week by Trichoscope.

2.2.2 Secondary Outcome

1. To assess overall improvement and the patient satisfaction by using Modified Global Photographic Assessment Score and Patient's Satisfaction Score.

2. To assess the adverse reactions of the combination treatment of Korean Red ginseng (Panax ginseng) and Vitamin B5 by using research questionnaire.

3. BACKGROUND

Nowadays, alopecia becomes the common problem for both men and women (Truong & Jeong, 2021). Roughly, 60% of men undergo androgenetic alopecia by 50 years of age. The risk is raised up to 80% by 70 years of age and more. Although, androgenetic alopecia occurs in considerable population, the frequency and severity are found to be reduced in women than in men (Kang, 2019).

Androgenetic alopecia (AGA) is a chronic condition in which the hair loss is gradual and progressive which principally seen in a person who has the strong genetic history. Currently, minoxidil (MNX) and finasteride are mainly used for alopecia patients although their effects are transient. Due to their side effects and limitations, the treatment is still quite challenging for dermatologists (Kelly et al., 2016). Therefore, scientists and dermatologists are emphasizing in research process to create new treatment option for both preventing and treating hair loss (Truong & Jeong, 2021).

Korean Red ginseng (Panax ginseng C. A. Meyer) contains unique content which is known as ginsenosides which are Rb1, -Rb2, -Rc, -Rd, -Rg3, -Rg1, and -Ro. Theses ginsenosides are primarily responsible for hair follicle regeneration, prevention of hair loss, anti-aging properties, antioxidant actions and anti-inflammatory action. Many clinical trials have already stated that oral taking of Korean Red ginseng improves hair length and density in alopecia patients (Truong & Jeong, 2021).

D-panthenol, pro-vitamin B5 is a famous for its anti-inflammatory and hydration effects, has been used in so many hair care products for hair growth and anti-hair loss. There were previous studies stated that oral D-panthenol taking can improve both female pattern hair loss and male androgenetic alopecia (Shin et al., 2021). The two factors involving in the formation of androgenetic alopecia which are free radical oxygen species and follicular inflammation can be inhibited by D-panthenol (Kutlu, 2020).

By using the Korean Red ginseng and D-panthenol which is a pro-vitamin B5, the pathogenesis of the androgenetic alopecia can be prevented and reverse. The activity of the enzyme 5α-Reductase is downregulated by ginsenosides of Korean Red ginseng which consequently suppress the activity of dihydrotestosterone. Additionally, with the combination effects D-panthenol and Korean Red ginseng, the infamous TGF-β pathway that causes multiple pathogenesis of hair loss can be prevented. The inflammation of hair follicle that resulted by TGF-β can be suppressed by D-panthenol. Furthermore, Korean Red ginseng and D-panthenol have the properties that can generate the hair growth and anti-apoptosis of the hair follicles. Because of all above mechanisms, the combination of Korean Red ginseng and D-panthenol can be used as alternative treatment for androgenetic alopecia. Additionally, Korean Red ginseng & Vitamin B5 are safe, costly and easily accessible agent throughout the world.

4. STUDY LOCATION

Mae Fah Luang University Hospital, Bangkok

5. PROCEDURE

12 volunteers will be enrolled according to inclusion and exclusion criteria. The researcher will explain detail about the purpose and treatment procedure including the

benefit and possible side effects after treatment. After that, researcher will take a written informed consent form from each volunteer. General information of the volunteers including personal profiles, previous medical history, and history that are related to research study. Before applying the hair lotion to the scalp, patch test for Korean Red Ginseng and Vitamin B5 was done to each volunteer. Hair count and hair thickness assessment will be elucidated by using trichoscope "Aramo® SG Skin and Hair Diagnosis System". Modified Global Photographic Assessment Score was done by using the digital camera for the baseline, photographic images were be taken in 2 positions of head; Vertex position and Forehead position. The researcher will explain to each volunteer how to apply hair serum.

Instruction for application of hair lotion.

1. Hair lotion is applied to the baldness areas of the scalp twice a day: in the morning and at night. 1 ml of hair lotion is used in each time with a dropper.
2. Hair lotion should only be applied 2 hours after washing and drying the hair.
3. After the application of hair lotion, give a gentle massage to the areas of baldness.
4. Avoid activities that cause excessive sweating and using hair dryer after application.
5. Volunteer should not be taken any other hair treatment during the research period.
6. If any adverse reactions are observed, stopped immediately.

Follow up Visit (4^{th}, 8^{th} and 12^{th} week)

Each follow-up visit, the researcher took a photograph of each subject by using identical camera setting the same light and the same position as before treatment. Photographic will take in 2 positions of head for assessment of Modified Global Photographic Assessment Score (MGPA score): Vertex position and Forehead Position. All subjects will be measured hair count (hair density) and hair thickness (hair diameter) by using trichoscope "Aramo® SG Skin and Hair Diagnostic System". All participants will be evaluated participant's satisfaction by using Participant's satisfaction Score. Any adverse reaction occurred to the participants at follow up visit will be evaluated by research questionnaire.

APPENDIX C

RESEARCH PROFILE (CONFIDENTIAL)

General Information (Only official)

1. Date
2. Sex o Male. o Female
3. Pregnancy o Yes o No
4. Occupation -
5. Underlying disease:
6. Personal medication and supplement:
    a. Chemo-radiotherapy
    b. Active inflammatory skin disease
    c. History of malignant of premalignant lesions in the treatment area
7. History of food or drug allergy:

    Allergic history to Korean Red ginseng.

    Allergic history to Vitamin B5.

    Contact dermatitis
8. Current treatment:
9. History of following treatment before the study

    o Yes (within 6 months) ...Identify

    Minoxidil Hair lotion

    Oral Finasteride

    Previous history of hair transplant

    o No

APPENDIX D

PHYSICIAN RECORD FORM

RESEARCH RECORD: (RESEARCHERS' PART)

EFFECTIVENESS OF THE COMBINATION TREATMENT OF KOREAN RED GINSENG AND VITAMIN B5 IN ANDROGENETIC ALOPECIA

ID.........................

Tasks at the first visit

Date ..../......................../..............

Please use (□) symbol

Check list for the first visit Process		
Process	Yes	No
Physical examination for fitness of the volunteer		
The volunteer has completed research profile		
All of the profile data is fit to selection criteria		
Assure that the volunteer can understand information in appendix and how to care his or her face after treatment		
The volunteer has written the informed consent form		
The researcher asked the volunteer for any curiosity		
The researcher answered the volunteer's questions		
Photography of the scalps were performed		
Hair count (hair density) & Hair Thickness (hair diameter) assessment by using trichoscope were performed		

CASE RECORD FORM, CRF

ID ………………………

1. Hair Count (hair density) assessment by using Trichoscope

Hair Count (Hair Density)	Value
Baseline	
Week 4th after final session	
Week 8th after final session	
Week 12th after final session	

2. Modified Global Photographic Assessment Score (MGPA score) by 3 Dermatologists

Baseline	Week 4 after final session	Week 8 after final session	Week 12 after final session

1 = Significant disease progression
2 = Moderate disease progression
3 = Slight disease progression
4 = No change is seen
5 = Slight improvement
6 = Moderate improvement
7 = Significant improvement

*Baseline MGPA= 4

APPENDIX E

QUESTIONNAIRE

แบบสอบถามความพึงพอใจของอาสาสมัคร

รหัสอาสาสมัคร ....

1. อาการข้างเคียงที่ไม่พึงประสงค์

โปรดใส่เครื่องหมายถูก (✓) ลงในช่องว่างที่มีอาการไม่พึงประสงค์หลังการรักษาในแต่ละครั้ง

อาการ	ใช่	ไม่ใช่	ระยะเวลา	หมายเหตุ
แดง (Redness)				
การระคายเคือง (Irritation)				
อาการคัน (itchiness)				
อื่นๆ				

2. คะแนนความพึงพอใจ

การประเมินความพึงพอใจ โดยอาสาสมัคร (โปรดทำเครื่องหมายวงกลม ○)

-1	0	1	2	3	4

-1 หมายถึง ไม่พึงพอใจ

0 หมายถึง ไม่แตกต่างจากเดิม

1 หมายถึง พึงพอใจระดับน้อย

2 หมายถึง พึงพอใจระดับปานกลาง

3 หมายถึง พึงพอใจระดับมาก

4 หมายถึง พึงพอใจที่สุด

3. หากเลือกได้ ท่านยินดีที่จะรับการรักษาแบบเดียวกันนี้ในอนาคตอีกไหม

☐ รับ ☐ ไม่รับ

CURRICULUM VITAE

NAME	Phoe Pyi
EDUCATIONAL BACKGROUND	
2018	Bachelor of Medicine and Bachelor of Surgery, University of Medicine 1, Yangon, Myanmar.
WORK EXPERIENCE	
2025 - Present	Research Medical Volunteer Maimonides Hospital, Brooklyn, New York, USA.
2023 - Present	Medical Assistant/Medical Scribe Brooklyn Medical Clinic (Cardiologist Dr. Abdul Malik), Brooklyn, New York, USA.
2019 - 2020	Civil Service (Junior) Medical Officer Yangon General Hospital and Yangon Specialty Hospital, Yangon, Myanmar
2018	Volunteer Medical officer Jivitadana Sanga Hospital (Hospital for Monks and Nuns), Yangon, Myanmar.
2016-2017	Internship West Yangon General Hospital (General Surgery, Pediatric) Internship East Yangon General Hospital (Ob-Gyn) Internship Yangon General Hospital (General Medical)