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A Randomized, Double-Blind, Placebo-Controlled, Single-Center Clinical Study to Assess the Efficacy and Safety of the "Folloemi: Hair Growth Serum" in Promoting Hair Growth, Reducing Hair Loss, Improving Hair Thickness, and Preventing Premature Greying of Hair

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Abstract

Background: Hair growth serums target and combat hair concerns like androgenetic alopecia, hair loss, thinning hair, and premature greying. These issues can arise from factors like genetics, hormonal imbalances, stress, poor nutrition, and environmental influences. Nutrient deficiencies, specifically biotin, iron, and zinc, can contribute to hair loss and thinning. Hair thinning is also linked to aging, hormonal changes, and inadequate nutrition. The objective of the study is to evaluate the efficacy and safety of hair growth serum in promoting hair growth, reducing hair loss, improving hair thickness, and preventing premature greying of hair. **Material & Methods:** The Clinical study conducted to assess efficacy and safety of investigational product. Trichoscopic analysis measured hair count/density and premature greying from baseline to 6 months, while hair thickness was assessed via trichoscopy. Hair loss reduction was measured using a comb test. **Results:** The Test Product demonstrated significant improvements, including a 35.80% increase in hair density, a remarkable reduction in greying hair (40.31% vs. 1.02% for Placebo), a substantial 79.92% improvement in hair thickness, and an impressive 82.30% reduction in hair loss. Notably, the product was found to be safe, with no reported adverse or serious adverse events. **Conclusion:** The test product proved to be highly effective in promoting hair density and addressing common hair concerns as hair density, greying hair, and hair loss count. These results demonstrated the efficacy of the test product as an advanced solution for improving overall hair health and managing hair-related issues.

Keywords:- Hair Loss, Hair Count, Premature Greying Hair, Hair Thickness, Serum and Scalp.

INTRODUCTION

Hair loss is a universal distressing condition involving genetic, nutritional, medical, and environmental factors. Hair fall is a widespread problem among all genders, ages, and ethnicity with both physical and psychological effects. It is a universal distressing condition involving genetic, nutritional, medical, and environmental factors. Human beings are born with approximately 100,000 terminal hair follicles on the scalp that are predetermined to grow long and thick hair.[1] Any or all of these elements, including stress, pollution, hormones, climate, and water quality, can affect hair growth. Hair problems such as balding,

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alopecia, and thinning hair are becoming more common in people of all ages as exposure to these factors increases. Hair thinning can be caused by a variety of factors, including aging, hormonal changes, and nutrient deficiencies. It can also be caused by styling practices such as heat styling and chemical treatments, which can weaken the hair and cause breakage.[2] Hair thinning can also be a symptom of an underlying medical condition, such as thyroid problems or anemia. By adding hair growth serums to your regular hair care regimen, you can stop this domino effect. As Folloemi is a potent hair growth serum which is hair follicle enhancer and rejuvenator used for Androgenetic Alopecia, Hair Loss, Thinning Hair and Premature Greying of Hair. Hair loss, or alopecia, is a condition in which hair in some area of the scalp is lost or no longer regrowth.[3] There are many types of hair loss, such as androgenetic alopecia (AGA) and alopecia areata (AA). Hair loss is caused by genetic factors and external factors especially prominent in modern society, such as work stress, emotional change and hormone secretion disturbance. Its prevalence tends to be among the young and it may result in disturbed self-perception and psychological conflict. Nowadays, it is becoming a worldwide issue for all ages.[2] Research has connected CoQ10 with increased cellular energy and blood flow which can help support the high energy demands of your hair follicles,[4] CoQ10 Stimulates the gene expression of hair keratins.[5] As a novel target for the induction of hair growth TERT (telomerase reverse transcriptase) overexpression in skin activates resting hair follicle bulge stem cells, which triggers initiation of a new hair follicle growth phase and promotes hair synthesis.[6] Activates resting hair follicle bulge stem cells, Initiates new hair follicle growth phase and Promotes hair synthesis. To Regulated the gene expression of cytokines,[6] such as IGF-1 and KGF (Keratinocyte Growth Factor), Activate the b-catenin pathway, TGF-b1, maintains hair follicle stem cells. Everyone has their own way of unwinding after a long, hard day. Resveratrol is the plant compound found in a glass of red and a variety of other foods. It boasts impressive health benefits, including helping with hair loss, reducing the signs of aging and even lifting depression and anxiety. Resveratrol induces a shift from Telogen to Anagen,[6] in the hair follicle by inducing proliferation of hair follicle bulge stem cells, thus promoting hair growth also believed to boost mitochondrial function and, in turn, the energy production of the hair cells. This helps keep hair follicles healthy and young. Resveratrol increased the hair shaft length of HFs and delayed the entry into catagen and also proliferated HDPCs (human dermal papilla cells) and prevented oxidative damage.[2] Procyanidin B-2 is a type of flavonoid that is found in a variety of plants, including apples and cocoa. It is believed to have a variety of health benefits, including the potential to improve hair growth,[7] here procyanidins stimulate anagen induction in hair cycle progression and stimulate proliferation of hair keratinocytes better than other flavonoids.[8] Where Topical Procyanidin in the telogen phase led to significant hair regeneration.[8] As Procyanidins selectively promote the growth of hair epithelial cells,[8] Procyanidin-B protects Hair Epithelial Cells from apoptosis and catagen induction.[9] In recent years the use of antioxidants as a functional ingredient in the diet of people increased significantly. A popular ingredient

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considered to be an antioxidant is collagen in its hydrolyzed form. Collagen peptides improve hydration and prevent MMP induced damage to ECM,[10] Marine peptides increase hair shaft diameter & decrease hair loss.[11] Rosemary Oil has many amazing benefits. This oil is known for stimulating hair growth, improving dry skin conditions, and increasing mental focus.[12] Rosemary Oil has antioxidant, antibacterial, antifungal, and anti-inflammatory properties. Enhances microcapillary perfusion. As effective as 2% Minoxidil for increase in hair count.[13] and it is Free from Sulphates, Parabens, Phthalates, Alcohol, Synthetic Colors & Fragrances. Astaxanthin inhibits both 5α-reductase and aromatase (promotes hair growth).[4] A potent antioxidant, improves blood flow, mitochondrial function and biogenesis,[5] Lauric acid inhibits 5α reductase I and II, reduces DHT formation and helps treatment of AGA.[6] Carnosine is a chelating agent & inhibits AGEs and ALEs formation. Carnosine has been shown to modulate ECM by suppressing TGFβ production.[14] Carnosine delays cellular senescence and rejuvenates senescent mammalian cells and enhances proteolysis of aberrant polypeptides, aiding proteostasis.[15]

MATERIAL AND METHODS

This was a randomized, double-blind, placebo-controlled, single-center clinical study conducted by a skilled investigator in India to assess the efficacy and safety of a hair growth serum in promoting hair growth, reducing hair loss, improving hair thickness, and preventing premature greying of hair. The study was initiated after receiving written approval from the Ethics Committee. 18-65 years aged men and women were enrolled with a diagnosis of Androgenetic Alopecia, Hair Loss, Thinning Hair and Premature Greying of Hair. Those suffering with hair loss due to pregnancy or breastfeeding or allergic to any of the ingredients in the hair growth serum were excluded from the study. To ensure fair and unbiased results, participants were prohibited in case they had a history of using hair growth treatments within the past 3 months. The hair growth serum contained a combination of active ingredients that have been shown hair growth, reduce hair loss, improve hair thickness and prevent premature greying of hair while the placebo was a similarly packaged and scented substance that does not contain any active ingredients.

Participants were tutored to wash their hair before the serum application and apply the investigational product directly to their scalp using cotton pad or finger tips twice or thrice in a week at night or at least for a 5-6 hours period before hair wash for 6 months. Quantity should not be more than 5ml. Hair counts and thickness measurements were taken at baseline and at 3 months and 6 months after treatment initiation.

In this study, several endpoints were used to evaluate the efficacy of the hair growth serum. Hair loss count was measured using the comb test which is a non-invasive and simple method that involved running a standard comb through the hair and counting the number of hairs that were lost. The comb test was performed at over the study visits to assess the change in hair loss count.

The diameter and density of hair follicles, as well as the presence of premature greying, was assessed using trichoscopic analysis which is a non-invasive technique that allows for the

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examination of the scalp and hair using a dermatoscope or trichoscope.

RESULTS

A total 100 subjects were enrolled in this clinical study. All subjects were equally divided into two group randomly some in test group and others are in placebo group.

Efficacy Endpoints

The objective of the study to evaluate the change in hair count/density and premature greying of hair over a six-month period, as measured by Trichoscopic analysis. Trichoscopic Hair Analysis is a computerized method to determine the condition of hair density, the status of hair roots and scalp conditions. It also evaluates hair thinning, which reveals your hair structure. It calculates responses to treatment in patients with pattern alopecia, enables a precise follow up of hair densities and much more. Unlike traditional methods of hair analysis that rely on visual observation, trichoscopic analysis uses specialized software to assess hair density, hair thickness, and the severity of premature greying in different areas of the scalp. This enables a more precise and accurate assessment of treatment efficacy over time, reducing the potential for subjective error.

To conduct the trichoscopic analysis, we selected a 1 cm^2 area in five different zones of the scalp named as frontal region, vertex, right and left temporal regions, and the occipital region. The software was used to analyze the average number of hair in each zone to assess the distribution and severity of premature greying of hair in different areas of the scalp. This type of analysis provided objective and precise information on the changes in hair count/density and premature greying over time. Through the software, we got a faster and more accurate assessment of the trichoscopic images and dropped the human error possibility in hair counting and measurement.

As observed from [Table 1], Subjects were divided equally and test were done by using trichoscopy over smaller section of each five areas of the scalp, and the number of hair stands within that area was counted. The hair density is then calculated by dividing the total number of hair strands by the area of the scalp measured per cm2. With only 4.64% changes, this analysis revealed that there was no significant change in placebo group with respect to hair density from baseline to EOS. Meanwhile in test group result showed that there was a significant increase in average hair density over scalp with 35.80% improvement from baseline to EOS. This advocated that the treatment had a positive impact on hair growth and density. The increase in hair count/density could be attributed to the stimulation of hair follicles or the improvement of scalp health.

Trichoscopy is a non-invasive technique that can be used to assess the hair follicles and surrounding skin. We used a standardized protocol to capture images of the scalp and hair, which were then analyzed using specialized software to determine the premature greying of hair and hair thinning over the course of the study. For assessing the hair thinning and premature greying of hair, the number of hair over a specific area of the scalp was counted. Trichoscopic analysis was used to assess hair thinning as it allows for the visualization and quantification of hair density and hair shaft thickness. In trichoscopy, the hair was

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magnified and the density, thickness, and diameter of the hair shaft was measured in a specific area of the scalp. This helped in diagnosing the underlying cause of hair thinning and monitoring the effectiveness of the treatment. After using test product intervention/treatment regularly as commanded in the protocol displayed the positive result of slowing down or even reversing hair thinning, improving the overall individual hair health.

The results in [Table 2] demonstrated a significant reduction in greying hair with the test Product compared to placebo (40.31% vs. 1.02%, respectively). This suggested that the treatment is effective and might lead to a decrease in the number of white or grey hair strands over time. Mean number of white hair analysis used to monitor changes in the amount of white or grey hair during treatment and to determine the effectiveness of the treatment.

Hair thickness (measurement of hair shaft diameter) was evaluated through micrometer from baseline to 6 months. Thicker hair strands tend to be stronger and more resilient to damage, while thinner hair strands may be more prone to breakage and hair loss. This measurement was used to compare the hair thickness between randomized groups or to monitor changes in hair thickness over time. To evaluate the same, a small section of hair was selected, and the hair strands were carefully separated from one another. The micrometer is then used to measure the diameter of individual hair strands, which could range from 20 µm to 180 µm or more, depending on the individual's hair type and other factors.

Study data showed that study population from each group has issue of hair thickness at baseline. [Figure 1] showed the increment in test product by end of the study visit.

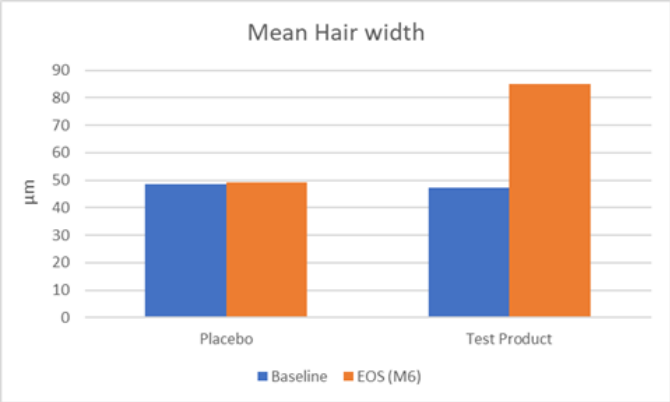

Figure 1: Change in Hair thickness/width from baseline to end of the study visit.

In this study, hair loss count was measured using the comb test. The test was performed by instructing the participants to wash their hair with a mild shampoo and let it air dry. The participants were then asked to comb their hair over a white paper for 3 minutes using a standard comb. The number of hair that felt out during the combing process were counted and recorded. This procedure was repeated at baseline, visit 02 and visit 03. The difference in hair loss count was calculated and analyzed for statistical significance using appropriate methods. The results showed a significant reduction in hair loss count after 6 months of using the hair growth serum compared to baseline. These findings suggested that the hair growth serum was effective in reducing hair loss in individuals suffering with androgenetic alopecia, hair loss, thinning hair, and premature greying of hair.

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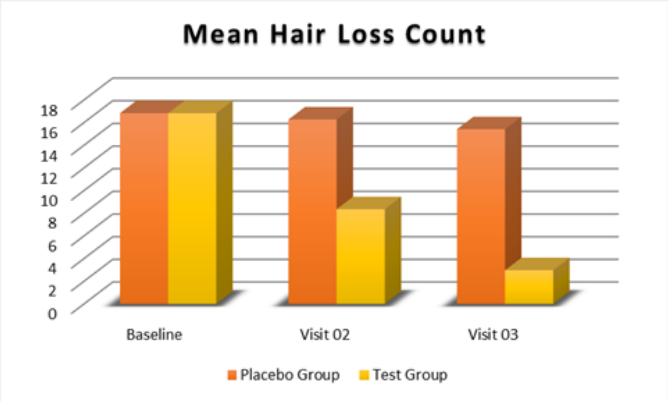

Figure 2: Change in hair loss count from baseline to end of the visit.

Data demonstrated in the above [Table 3 and Figure 2], were collected by using comb test. Study subjects had same number of mean at baseline in both groups, the decline was shown in next visit -02 and as the continuation decline showed a successful result at the end of the study. Test group achieved 82.30% reduction in hair loss over a six-month span. On the other side placebo shows only 8.43% improvement.

Safety endpoints

There were no adverse events recorded with respect to any local skin reactions, scalp irritation, and systemic side effects. However, there was no serious adverse event reported during the study conduct.

Table 1: Mean Hair Density (Hair/cm2)

	Frontal	Vertex	Right temporal	Left temporal	Occipital	Average Hair density over the scalp	Change from baseline to EOS (%)
Placebo							
Baseline	120.4	126.5	115.6	112.1	118.5	118.62	5.5 (4.64)
EOS	127.4	128.1	120.6	121.2	123.3	124.12	
Test Product							
Baseline	122.6	125.2	114.3	113.2	118	118.66	42.48 (35.80)
EOS	174.23	172.1	145.2	152.4	161.8	161.146	

Table 2: Mean Number of White Hair (Hair/cm2)

	Frontal	Vertex	Right temporal	Left temporal	Occipital	Average White Hair over the scalp	Change from baseline to EOS (%)
Placebo							
Baseline	20	16.3	12.2	11.2	8.6	13.66	0.14 (1.02)
EOS	19	17	11.8	11.3	8.5	13.52	
Test Product							
Baseline	21.3	15.8	12.2	12.3	9.1	14.14	5.7 (40.31)
EOS	14.1	9.1	7.5	6.2	5.3	8.44	

Table 3: Change in hair loss count from baseline to end of the visit

	Baseline	Visit 02	Visit 03	Change from baseline to EOS
Placebo Group	16.84	16.28	15.42	1.42 (8.43%)
Test Group	16.84	8.36	2.98	13.86 (82.30%)

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DISCUSSION & CONCLUSIONS

Hair loss and premature greying of hair are common problems that affect a significant portion of the population, both men and women alike. These issues can lead to a decrease in self-confidence and self-esteem, negatively impacting overall well-being. A variety of treatments are available on the market, including medications, supplements, and topical solutions. However, many of these treatments are associated with unpleasant side effects, limited efficacy, or are prohibitively expensive.

In recent years, there has been a growing interest in the development of safe hair care products that can help reduce hair loss and premature greying without the drawbacks associated with conventional treatments. Despite the popularity of natural hair care products, the scientific evidence supporting their effectiveness in preventing hair loss and premature greying remains limited. This study aims to address this gap by evaluating the efficacy of the hair serum in reducing hair loss and premature greying of hair.

The study results concluded that Folloemi Hair serum not only marked a visible improvement in hair density and thickness, but also the reduction in hair loss and premature greying of hair. It resulted 35.80% improvement in hair density, 40.31% reduction in hair greying, 79.92% improvement in hair thickness along with 82.30% reduction in hair loss. Also, the product was found to be safe as no Adverse or serious adverse event was occurred during the study period. It determined that Folloemi Hair serum worked as a hair follicle enhancer and rejuvenator.

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