



### Research Article

## Randomized controlled trial to assess the efficacy and safety of Facia Men's capsule for hair loss

**Jayasiri APA<sup>1</sup>, Hapuarachchi SD<sup>2\*</sup>, Perera PK<sup>3</sup>, Weerasekara KR<sup>4</sup>, Dahanayake JM<sup>5</sup>, Kodithuwakku ND<sup>6</sup>, Karunagoda KPKR<sup>7</sup>, Gunarathne EDTP<sup>8</sup>, Liyanage UP<sup>9</sup>, Kaushalya HBD<sup>10</sup>, Bandara AMNV<sup>11</sup>, Jayasuriya HGSV<sup>12</sup>**

1-3. Professor, Department of Ayurveda Pharmacology, Pharmaceutics and Community Medicine, Faculty of Indigenous Medicine, University of Colombo, Sri Lanka.

4. Professor, Department of Ayurveda Medicine and Indigenous Medicine, Faculty of Indigenous Medicine, University of Colombo, Sri Lanka.

5,6. Senior Lecturer, Department of Ayurveda Pharmacology, Pharmaceutics and Community Medicine, Faculty of Indigenous Medicine, University of Colombo, Sri Lanka.

7. Professor, Department of Ayurveda Surgery, ENT, Ophthalmology and Gynecology, Faculty of Indigenous Medicine, University of Colombo, Sri Lanka.

8. Senior Lecturer, Department of Ayurveda Medicine and Indigenous Medicine, Faculty of Indigenous Medicine, University of Colombo, Sri Lanka.

9. Senior Lecturer, Department of Mathematics, Faculty of Science, University of Colombo, Sri Lanka.

10,11,12. Research Assistant, Department of Ayurveda Pharmacology, Pharmaceutics and Community Medicine, Faculty of Indigenous Medicine, University of Colombo, Sri Lanka.

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### Abstract

Excessive thinning and losing of hair are prominent symptoms of hair loss, which can significantly lower an individual's quality of life. This randomized, open label-controlled, clinical trial observed at the effectiveness and safety of Facia Men's capsule for treating male pattern hair loss. Facia Men's capsule includes extracts of *Serenoa repens* dry fruits and *Cucurbita pepo* seeds, vitamins and minerals that help with hair growth and reduce shedding. A total of 126 male participants aged between 18 to 45 years with androgenetic alopecia were evenly split into intervention and control groups. Participants in the treatment group were instructed to take two capsules twice daily over a 12 weeks intervention period. No treatment given for the control group. Effectiveness was measured using daily hair loss counts, shampoo hair counts, hair pull tests while safety study was monitored 12 weeks utilizing Serum Creatinine, Alanine aminotransferase, Aspartate aminotransferase, and fasting blood sugar. The results showed a significant reduction in hair shedding across all subjective and objective measures in the treatment group compared to the placebo group ( $p < 0.001$ ). No significant changes appeared in tests for renal and liver function, confirming safety. In terms of average hair fall counts, above 60% improvement has been observed among the treatment group. There was a small but statistically significant change in fasting blood glucose, which suggests the need for future monitoring of metabolic health. These findings indicated that Facia Men's capsule is an effective and safe herbal option for managing male pattern hair loss.

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## Introduction

Hair loss, or alopecia, is a prevalent condition affecting individuals across all age groups in society. Although it is not a

life-threatening condition, hair loss can significantly impact quality of life and psychological well-being. Both males and females are susceptible to various forms of alopecia throughout their lifetime. Hair loss is a natural occurrence in the hair growth cycle. The condition of hair fall dominates the hair growth, identified as hair loss or hair fall condition. Hair loss is a prevalent concern arising from multiple etiologies, including hormonal alterations, psychosocial and physiological stress, nutrient deficiencies, pharmacological agents, environmental exposures, lifestyle factors, and changes in scalp or hair care habits (1-6). More specifically, different causes for the hair loss can be stated, like androgenetic alopecia (AGA), medical conditions such as hypothyroidism, use of contraceptives, and nutrition deficiencies

### \* Corresponding Author:

#### Hapuarachchi S D

Professor, Department of Ayurveda Pharmacology, Pharmaceutics and Community Medicine, Faculty of Indigenous Medicine, University of Colombo, Sri Lanka.

Email Id: [dr.sdhapuarachchi@fim.cmb.ac.lk](mailto:dr.sdhapuarachchi@fim.cmb.ac.lk)

(1,2). Among these reasons, nutrition plays a significant role in hair loss, as it directly affects the hair growth cycle. During the lifespan, hair loss occurs in both males and females, with males commonly experiencing it at a younger age. However, hair loss is more prominent in approximately 80% of males, while affecting about 50% of females. The incidence of hair loss increases with age and is most prevalent in Caucasians, followed by Asian and African American populations, and finally in Native Americans and Eskimos (7). Humans are usually born with around five million hair follicles, and there will not be any new additions after birth. Hair loss naturally progresses gradually and is commonly associated with aging. However, features can vary depending on the type and severity of the condition, and they can vary from person to person. Some individuals may experience a combination of alopecia (hair loss) of different types as well (8). The current prevalence of hair loss as a disease condition was found to be 60.3%, and baldness was 50.4% concerning global statistics (9). In the development of hair care products, it is essential to consider the growth pattern of hair and design an effective product to address the individual hair problems of the victim. Therefore, it is necessary to identify the cause and apply a suitable product to treat the condition. Hair follicles are dynamic micro-organs, and each hair follicle is a regenerative system that physiologically undergoes a continuous cycle of anagen, catagen, and telogen phases. The anagen phase is the active phase of the hair follicle and is the most essential determinant of hair length and thickness. The transition from the anagen phase to the catagen phase is mediated by key hair growth regulatory factors, namely, Insulin-like Growth Factor 1 (IGF- 1) that maintains growth, and Transforming Growth Factor-  $\beta$ 2 (TGF-  $\beta$ 2) that promotes hair growth (10-12). Thus, higher expression levels of IGF- 1 and lower expression levels of TGF-  $\beta$ 2 are beneficial for maintaining the anagen phase. Research has shown that in patients with androgenetic alopecia (AGA), the hair growth cycle undergoes significant changes (13). Specifically, the androgenetic (growth) phase becomes shorter, while the telogen phase is prolonged. These alterations can lead to a reduction in the diameter of the hair follicles, contributing to hair thinning and loss. Currently, available drugs cause certain side effects; therefore, natural products are safer to use even for a long time (14).

### Facia men's soft gel capsule (FMC)

Facia men's soft gel capsule (FMC) is a herbal product made out of mainly extracts of *Serenoa repens* (W. Bartram) Small and *Cucurbita pepo* L. seed oil. According to studies, saw palmetto is rich in natural 5-alpha reductase (5 $\alpha$ R) inhibitors, which play a significant role in hair shedding (15). Pumpkin (*Cucurbita pepo* L.) seed oil mainly consists of saturated and unsaturated fatty acids. Along with these two herbs, the following ingredients are included in this product: Riboflavin, Nicotinamide, Vitamin A palmitate, Cysteine hydrochloride, Calcium pantothenate, d-Alpha Tocopherol, Biotin, Zinc amino acid, Collagen, Hydrogenated coconut oil, yellow beeswax, Soy oil, Lecithin, Gelatin, Glycerol, Titanium dioxide, and purified water (16). Individually, these ingredients possess properties that promote hair growth, prevent shedding, and support skin care, among others. Therefore, this study is both timely and qualitatively suitable for general use (17-22).

## Materials and methods

### Ethics approval and consent to participate

The study protocol and other relevant documents were approved by the Ethics Review Committee of the Faculty of Indigenous

Medicine, University of Colombo, Sri Lanka (Project No. 24/227), and the consent of all participants was obtained during registration for this clinical trial.

### Study design

The study was conducted as a randomized, open label-controlled clinical trial design to investigate the effect of Facia men capsules on hair loss. The suitable subjects were selected in accordance with the computer-generated random number list (n=100/group). The sample size was calculated according to the method outlined in the WHO practical manual (23).

$n_1, n_2$  = Sample sizes

$Z_{\alpha/2}$  = For Critical value of 95% confidence interval (1.96)  $Z_{\beta}$  = For 95% Power (0.05)

$\alpha$  = The probability of type I error (significance level) is the  $\beta$  = The probability of type II error (1 – power of the test) is the

$\mu_2 - \mu_1$  = The value of allowable difference is the true mean difference between a test drugs ( $\mu_2$ ) and a placebo control or active control agent ( $\mu_1$ ).

Sample size of each group = 63

### Inclusion criteria

- Healthy male volunteer individuals
- Age between 18-45 yrs
- Who can provide written informed consent
- Androgenetic alopecia type patients
- Those who do not use any hair care medication, chemotherapy, or other drugs to treat any skin condition
- Those who do not have any treatments for hair loss, modify or color their hair and not to wear instruments that have traction force on hair

### Exclusion criteria

- Individuals with any known allergy to any of the test formulations and with a complex or severe drug allergy.
- Who are suffering from scarring alopecia types
- Who are suffering from non-scarring alopecia, except androgenetic alopecia
- Those suffering from other non-communicable diseases, such as diabetes
- Hair falling due to tinea capitis, pediculosis capitis, and other conditions.
- The participants who are consuming systemic steroids.
- Patients under systemic hormonal treatment
- Individuals undergoing specific treatments for dandruff, such as those involving minoxidil, products containing silicone, parabens, and various other hair care products
- Individuals with a history of or suspected malignancy and those who use drugs that cause significant hair loss
- Prior surgical scalp hair loss repair.

### Grouping and Intervention

After screening with the study selection criteria, 126 male patients with type hair loss were selected, as this type is the most common in Asia. The patients were attending the Outpatient Department (OPD) of National Ayurveda Hospital Sri Lanka (NAHSL). To assess the efficacy of the product, participants were randomly assigned using simple randomization and allocated into two groups in a 1:1 ratio. Randomization was based on randomly generated codes to prevent investigators and participants from predicting the results. The experimental group received Facia men's capsule, and no treatment was given to the control group.

Dosage is two capsules (850 mg) twice daily. The study was conducted for 12 weeks with a 14-day follow-up period.

## Study Assessments

### Parameters to evaluate the efficacy of FMC

**Responsive Parameters** - Daily hair loss count, 60-s hair count in shampooing days, Pull test/ Traction test

**Safety Parameters** - Serum Creatinine, Fasting Blood Sugar, Alanine aminotransferase (AST), and Aspartate aminotransferase (ALT)

### Daily hair loss count

The participants were asked to collect shed scalp hair throughout the day and gently collect it into a clean and sterile bag. All shed hairs in the shower, sink, or on the brush are collected. At the end of the day, the fallen hair count will be taken. If the count is less than 100, it is normal (1).

### 60-s hair count in shampooing days

The volunteers are advised to brush the hair for 60 seconds over a pillow or white sheet.

Count the number of hairs in the comb/brush and on the pillow or sheet and record (1).

### Hair Pull test

Approximately 20-60 hairs are dragged away from the head gently and firmly, by holding them between the thumb, index, and middle fingers near the scalp. If more than 10% hairs are pulled away from the scalp, this constitutes a positive pull test and implies active hair shedding (1).

All subjective and objective parameters were analyzed to evaluate the efficacy of the test product before treatment and after the follow-up period. To assess the safety of the product, all participants will undergo the following investigations before treatment and after the follow-up period. GFR, serum creatinine level, Alanine Aminotransferase (ALT), aspartate amino transferase (AST), and Fasting Blood Sugar (FBS) levels. A questionnaire used for patients' self-assessment, which has been shortlisted and psychometrically evaluated for validity.

### Statistical Analysis

The effectiveness of the treatments on hair loss over 12 weeks was assessed using standard comparison procedures (24). Normality conditions of samples were checked in determination of the statistical comparison procedure. However, normality conditions for all samples are rejected (Shapiro-Wilk test,  $p < 0.05$ ) for both

treatment and control groups, and thereby, non-parametric test: Wilcoxon signed-rank, was used to evaluate the changes in efficacy parameters before and after treatment within each group. The Mann-Whitney U test is used in testing the difference between control and treatment groups. The resulting p-values, indicating the statistical significance of observed changes, are presented accordingly.

## Results and discussion

Both the trial and control groups consisted entirely of male participants of 63 in each group. The mean age between the groups, does not show much variation. Thus, the groups are reasonably comparable in terms of demographic characteristics.

### Effectiveness of the treatments

The treatment demonstrated high efficiency within the treatment group, with substantial mean reductions observed across all hair fall indicators. The daily hair loss count decreased from 56.25 to 22.24, showing a mean reduction of 34.01 hairs. The efficacy parameter 60-second hair count on shampooing days, reduced from 19.13 to 7.73, a mean difference of 11.40 hairs, and the pull test count declined from 5.52 to 2.05, indicating a mean reduction of 3.47 hairs. Referring to Table 2 it is evident not only the hair fall counts been reduced but also the slandered deviation of those counts has been considerably reduced indicating hair fall counts across the treatment group is been controlled. This is a more than 60% reduction of the hair loss.

Concerning the statistical significancy, the daily hair loss counts decreased, showing a large reduction in treatment group (Shapiro-Wilk  $p = 0.00002$ , Wilcoxon signed-rank test  $p = 1.097e-10$ ). However, the control group daily hair loss count was not statistically significant, as shown in the Table 1. The hair loss count reduction of the treatment group is significantly larger to the control group (Mann-Whitney U,  $p = 0.0019$ ) at the end of the experiment. The 60-second hair count during shampooing days decreased significantly in the trial group, indicating a meaningful improvement. The mild decrease in the control group was not statistically significant (Shapiro-Wilk  $p = 0.4622$ ), but clinically modest. Further the decrease of the 60-second hair loss count of the treatment group is significantly large compared to the control group (Mann-Whitney U,  $p = 0.0000$ ). For the pull test, the trial group's count reduced substantially (Shapiro-Wilk  $p = 0.0000$ ). The control group also showed a count reduction, but this change was not significant (Shapiro-Wilk  $p = 0.0866$ ). These consistent and considerable reductions across all parameters highlight the treatment's ability to deliver strong results efficiently within the study period.

**Table 1: Effectiveness of the treatment of FMC**

Investigation	Trail Group				p-values*
	Before Treatments		After Treatments		
	Mean	SD	Mean	SD	
Daily hair loss count	56.2539	37.2766	22.2363	21.9856	5.483E-11
60-s hair count in shampooing days	19.1269	13.8779	7.7272	9.9003	1.587E-10
Pull test from 20 hair	5.5238	3.141	2.0545	1.8897	4.223E-10
Investigation	Control Group				p-values*
	Before Treatments		After Treatments		
	Mean	SD	Mean	SD	
Daily hair loss count	24.1587	9.2059	22.5161	9.2607	0.9999
60-s hair count in shampooing days	12.4126	7.2125	11.4354	7.2736	0.9999
Pull test from 20 hair	3.1904	1.5224	2.7096	1.4973	0.9999

\*values are lower than the before treatment compared to the after treatment (Wilcoxon sign rank test)

## Safety study of FMC on hair loss treatment over 12 weeks

Table. 2: Safety of the treatment of FMC

Investigation	Trail Group				Difference	
	Before Treatments		After Treatments		Test Statistics	p-values*
	Mean	SD	Mean	SD		
Fasting Blood Sugar (mg/dL)	90.2063	8.12038	89.2727	9.427	633.5	0.2523
Serum Creatinine (mg/dL)	1.01	1.0921	1.0383	1.1418	502.5	0.1998
AST(IU/L)	25.1111	7.1844	24.0909	7.3893	440.5	0.0865
ALT(IU/L)	42.0158	16.3918	38.8	15.6966	239.5	0.0017**

\* p-values are based on Wilcoxon signed-rank test; \*\* p-values are based on Wilcoxon signed-rank test and after treatment values are less than the before treatment value.

The safety of the drug on hair loss over 12 weeks was assessed using standard comparison procedures. Since the data for all parameters were not normally distributed (as confirmed by the Shapiro-Wilk test,  $p < 0.05$ ), the application of a non-parametric test was appropriate. Therefore, the Wilcoxon signed-rank test was used to evaluate the changes in safety parameters before and after treatment within each group. The resulting p-values, indicating the statistical significance of observed changes, are presented in Table 2.

Best on the exclusion and inclusion criteria, safety parameters have not indicated any abnormal disorders among the treatment group. After the experiment, no evidence has been discovered to indicate any significant changes of the fasting blood glucose levels ( $p = 0.2523$ ), suggesting that the drug does not adversely affect glycemic control. Similarly, no evidences illustrated in the changes of serum creatinine levels ( $p = 0.1998$ ). This indicates no detectable impact on renal function after the experiment. The difference in AST levels before and after treatment was not statistically significant ( $p = 0.0865$ ). However, concerning the ALT there is a statistical difference after the treatment ( $p = 0.0017$ ). Nevertheless, this difference is caused by the minor reduction of ALT levels after the treatment (Wilcoxon signed-rank,  $p = 0.0008$ ). AST and ALT levels consistency indicates no detectable impact on hepatic function. This illustrates, the safety measures are preserved by the experiment, as per the control range: Fasting blood glucose level 70 and 99 mg/dL (3.9 and 5.5 mmol/L), The normal range for Aspartate and Alanine Aminotransferases (AST and ALT) levels ( $<40$  IU/L) (25,26).

## Conclusion

According to the statistical analysis, there is a consistent and significant reductions across all efficacy parameters: Daily hair loss count, 60-s hair count in shampooing days, Pull test from 20 hair. Further, the reduction of the hair fall parameters shows more than 60% improvement on average after the experiment. Thus, the experiment results emphasize the effectiveness of the treatment FMC on hair falling control over the 12-week period. However, no such significant improvement is illustrated on the control group. Furthermore, the stability, i.e., no significant difference before and after treatments, of the safety parameters have ensured that the drug would not adversely affect glycemic levels and hepatoprotective parameters.

The experiment results and the associated statistical analysis illustrate that under the 95% confidence, the treatment FMC is effective and safe to use, concerning tested safety parameters.

## Data availability

The datasets generated and /or analyzed during the current study are not publicly available to protect the identity of the participants

but are available from the corresponding author on reasonable request.

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