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ORIGINAL RESEARCH

Targeted Follicular Delivery via Liposomal Encapsulation of *Sesbania grandiflora* - Enhances Hair and Scalp Health: A Randomized, Double-Blind, Placebo-Controlled Clinical Study

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Purpose: Hair fall results from disruption of the hair growth cycle, resulting in reduced hair density, thickness, and overall scalp health. With increasing interest in safer plant-based therapies, this study evaluated the safety and efficacy of a liposomal-encapsulated *Sesbania grandiflora* formulation 150 mg compared with placebo on hair and scalp health.

Patients and Methods: This single-center, randomized, double-blind, placebo-controlled study was conducted over 180 days (24 weeks) in adults aged 25–45 years with hair loss. Subjects were randomized 1:1 to receive once-daily liposomal *Sesbania grandiflora* 150 mg or placebo orally for six months, with eight scheduled visits. Outcomes included hair density, thickness, growth rate, keratin levels, hair length, anagen–telogen ratio, hair fall, hair regrowth, tensile strength, nail brittleness, laboratory parameters, and overall hair and scalp appearance assessed using calibrated bioinstrumentation and standardized methods.

Results: The liposomal *Sesbania grandiflora* group demonstrated significant improvement in all outcomes by day 180. Hair density (274.88±25.05 cm^2; $p < 0.0001$), hair thickness (9.53±1.28 µm;$p < 0.0001$), and hair growth rate (323.65±61.38 µm/day; $p < 0.0001$). Improvements were also observed in hair length (228.18±43.71 µm; $p < 0.0001$), anagen hairs (61.04±12.44%; $p < 0.0001$), and telogen hairs (38.96±12.44%; $p < 0.0001$). Keratin levels and scalp condition improved, accompanied by a reduced hair fall and enhanced hair regrowth (10.06±1.98; $p < 0.0001$). Hair tensile strength increased significantly (35,086.09±6,374.81 g/m^2; $p < 0.0001$). Adverse events were reported during the study; however, none were considered related to the product.

Conclusion: SesZenBio™, a biotin- and polyphenol-rich liposomal formulation, significantly improved hair and scalp health compared with placebo, evidenced by increased hair thickness, hair density, hair length, hair growth rate, anagen hair percentage, keratin, and tensile strength, along with a reduction in hair fall The formulation was well tolerated, supporting its potential as an effective plant-based product for the improvement of hair parameters.

Keywords: hair fall, hair growth rate, hair density, hair thickness, anagen-telogen hairs, keratin

Introduction

Hair loss is a common clinical and cosmetic concern with a multifactorial etiology that has a significant impact on quality of life. Alopecia is defined as partial or total hair loss, and is generally categorized as scarring or non-scarring. In scarring alopecia, irreversible destruction of the hair follicle results in permanent hair loss, whereas in non-scarring alopecia, follicular architecture is preserved, allowing the possibility of hair regrowth.[1] Among the non-scarring alopecias, androgenetic alopecia (AGA), generally referred to as male or female pattern hair loss, is the most common. This is marked by gradual hair thinning related to follicular miniaturization and reduction in the functional capacity of the affected follicles. Epidemiological data show that AGA affects more than 40% of adult males and approximately 30% of

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adult females.[2,3] In males, AGA usually shows up as thinning at the vertex and bitemporal recession. Women generally show diffuse thinning over the crown and a full-frontal hairline.[4]

The pathophysiology of AGA is multifactorial and includes a strong genetic component as well as abnormal metabolism of androgens. The main pathogenic mechanism involves the metabolism of testosterone to its active form, dihydrotestosterone (DHT), via the enzyme 5-α-reductase and the subsequent binding of DHT to androgen receptors in the hair follicle. Balding scalp follicles have higher concentrations of DHT, higher activity of 5-α-reductase, and higher expression of androgen receptors, making them more vulnerable to androgen stimulation. Genetic loci, such as the androgen receptor (AR) gene and ectodysplasin A2 receptor (EDA2R), are significantly associated with susceptibility to AGA.[4,5] At the follicular level, the main pathologic process is that terminal hair follicles get smaller over time, and terminal hairs turn into finer, vellus-like hairs. As this happens, the anagen phase becomes shorter, the telogen phase becomes longer, and hair density, hair shaft diameter, and visible scalp coverage decrease.[5]

Currently, topical minoxidil and oral finasteride are the most commonly used and US Food and Drug Administration (FDA)-approved pharmacological treatments for AGA, mainly focusing on miniaturized follicles and modulation of the hair cycle. However, the need for long-term, consistent use, possible side effects, and discomfort during treatment has sparked interest in adjunctive or alternative methods. Other FDA-approved therapies, such as low-level light therapy (LLLT), platelet-rich plasma (PRP), exosome-based therapies, and androgen-targeting approaches, seek to promote follicular activity and hair growth through different mechanisms.[6]

However, there has been growing interest in plant-based and nutraceutical supplements that promote hair and scalp health. Several botanicals, including *Acacia concinna, Camellia oleifera, Azadirachta indica, Emblica officinalis, Sapindus mukorossi*, and *Garcinia mangostana*, have traditionally been used in hair care products due to their beneficial physicochemical and biological properties. In recent years, Sesbania grandiflora has gained attention because it contains bioactive phytoconstituents such as biotin and polyphenols, which play important roles in keratin synthesis, energy metabolism, and antioxidant mechanisms.[7] Biotin is a key nutrient for maintaining hair strength, whereas polyphenols have been shown to reduce oxidative stress, thereby promoting a healthy scalp environment.[8]

Preclinical studies on standardized *Sesbania agati* leaf extract (SesZenBio™) have offered a mechanistic rationale for its potential role in hair biology. In silico analysis of the extract showed favorable drug-likeness and ADMET characteristics, and predicted molecular interactions with targets involved in hair follicle growth and differentiation. Analytical analysis of the extract confirmed a biotin content of approximately 0.5%, supporting the hypothesis that plant-derived biotin in combination with other cofactors could potentially promote follicular activity and hair health.[9] Furthermore, in vitro and ex vivo studies of the extracts showed stimulated hair cell proliferation and activation of the Wnt/β-catenin signaling pathway, a central mediator of hair follicle regeneration and stem cell differentiation.[10]

Generally, liposomal formulations are employed to enhance the bioavailability, stability, and targeted delivery of the formulation, thus protecting it from premature degradation and facilitating improved cellular uptake at the follicular level.[11] Compared with other nanoformulations, liposomes are biocompatible and structurally similar to biological membranes, which may improve penetration and targeted delivery of active ingredients to the hair and scalp.[12] It was predicted that compared with non-encapsulated formulations, this improved delivery system would allow for more effective biological activity and long-lasting follicular effects, resulting in improvements in hair and scalp health parameters. Based on the supportive preclinical and in silico evidence of the extract, the present randomized clinical study was designed to evaluate the safety and efficacy of liposomal-encapsulated *Sesbania grandiflora* formulation in adults experiencing hair fall in comparison with placebo. The primary evaluations included hair density, thickness, and growth rate. Secondary evaluations include keratin measurement, hair length, % Anagen-Telogen hairs, hair fall, number of new hairs, hair regrowth, hair root strength, general appearance of hair and scalp, tensile strength, product perception questionnaire, nail brittleness and lab parameters including hematological parameters such as Hemoglobin (Hb), Hematocrit (Hct), Red Blood Cell Count (RBC), Mean Corpuscular Hemoglobin (MCH), Mean Corpuscular Volume (MCV), Mean Corpuscular Hemoglobin Concentration (MCHC) and White Blood Cell Count (WBC), as well as biochemical parameters such as Serum Glutamic Oxaloacetic Transaminase (SGOT), Serum Glutamic Pyruvic Transaminase (SGPT), Serum Creatinine, Blood Urea Nitrogen (BUN), Random Blood Glucose (RBG), Post-Prandial Blood Sugar (PPBS), Total Cholesterol (TC), Triglycerides (TG), High-Density Lipoprotein (HDL), Low-Density

Lipoprotein (LDL), Very-Low-Density Lipoprotein (VLDL), Uric acid, C-Reactive Protein (CRP), Random Serum Cortisol, Serum Ferritin, Testosterone, Free testosterone and Dihydrotestosterone (DHT).

Materials and Methodology

Study Design

This study was conducted in accordance with the ICMR ethical guidelines, the International Council for Harmonization–Good Clinical Practice (ICH-GCP), and the Declaration of Helsinki. The study protocol (Ver#1.0) was approved by the ACEAS independent ethics committee on 20 Jul 2024, prior to commencement of the study procedures (Approval Number: NB240030-ZV). The study was registered with the Clinical Trial Registry of India (CTRI) under registration# CTRI/2024/08/071884 on 05Aug24 and additionally listed on ClinicalTrials.gov with Identifier NCT06551818. All subjects provided written informed consent prior to enrolment.

This was a prospective, interventional, comparative, double-blind, randomized, placebo-controlled study of the safety, efficacy, and in-use tolerability of plant-based oral liposomal hair growth products in subjects with mild to moderate Androgenic Alopecia (Grade I to III) for 180 days. A total of 39 subjects were enrolled, of whom 35 completed the study and were randomly assigned a 1:1 ratio. This study was conducted at NovoBliss Research Private Limited in Ahmedabad, India.

Subject recruitment commenced on 23 September, 2024, corresponding to the first subject's first visit (FSFV), and the study was concluded on 07 Jul 2025, corresponding to the last subject's last visit (LSLV). The study design ensured a consistent follow-up across all visits.

The primary evaluations included hair density, thickness, and growth rate. Secondary evaluations included keratin measurement, hair length, anagen and telogen hairs, hair fall, number of new hairs, hair regrowth, hair root strength, general appearance of hair and scalp, tensile strength, product perception questionnaire, nail brittleness, and laboratory parameters.

Study Visits and Assessments

Details of study visits and corresponding assessments are summarized in Table 1.

Test Product Details

Subjects were randomly assigned to receive one of two test products: liposomal form of *Sesbania grandiflora* 150mg capsule which containing biotin 0.5%, or placebo capsule filled with tapioca starch. The liposomal form of *Sesbania grandiflora* was manufactured and marketed by Zenherb Labs Pvt., Ltd. Both the test product and placebo were provided in identical containers to maintain a double-blind study design, and the assigned study product was administered orally as a single capsule once daily after a meal for the entire duration of the 180-day study. The capsules were swallowed with full glass of water (approximately 240mL) and stored at room temperature.

Formulation Development and Liposomal Encapsulation of Liposomal Sesbania grandiflora

A liposomal *Sesbania grandiflora* formulation was prepared using a standardized *Sesbania* extract obtained from the leaves as the active ingredient. The composition of the formulation included standardized Sesbania extract (50–55% w/w), gum acacia (35–40% w/w), and sunflower lecithin (10–15% w/w), with ethanol and purified water as sufficient quantity as processing solvents. Gum acacia is a natural stabilizer and carrier that inhibits the aggregation of liposomes and protects the active from degradation, thereby increasing stability and activity. It also helps in the formation of liposomes, thereby increasing the encapsulation and permeability of the extract, which improves bioavailability and controlled release. All raw materials were subjected to predefined quality control tests before formulation. Weighed quantities of the formulation materials were dissolved and processed to form a homogeneous mixture, which was further processed for homogenization under optimized conditions to enable liposomal encapsulation and the formation of a uniform dispersion. The homogenized dispersion was then spray-dried, cyclone-collected, and passed through a 40-

Table 1 Study Visits and Assessments

Visit 01 (Day −04)	**Screening, site marking, hair growth measurement**
Visit 02 (Day 01)	Enrolment, hair growth rate measurement, hair length (affected targeted area and standard area), hair thickness, hair density, scalp condition for keratin measurement, %Anagen-Telogen ratio, number of new hairs, number of hair fall from root, hair root strength, general appearance of hair, general appearance of scalp, earlier product perception questionnaire, global pictures of head crown, CBC, Biochemical tests, free testosterone, testosterone, dihydrotestosterone, CRP, Cortisol random, ferritin, urinalysis
Visit 03 [Day 45 (± 2 days)]	Hair Length (affected targeted area standard area), hair thickness, hair density, scalp condition for keratin measurement, hair regrowth (affected area), number of hair fall from root, number of new hair (from the head crown and normal scalp- tattoo area), hair root strength, general appearance of hair, general appearance of scalp, product perception questionnaire, global pictures of head crown.
Visit 04 [Day 87 (± 2 days)]	Site marking, hair growth rate measurement
Visit 05 [Day 90 (03 days from visit 04)]	Hair growth rate measurement, hair length (Androgenic Alopecia affected targeted area and standard area), hair thickness, hair density, scalp condition for keratin measurement, A: T ratio, hair regrowth (AG affected area), number of new hairs (on head crown and normal scalp- tattoo area), number of hair fall from root, hair root strength, general appearance of hair, general appearance of scalp, product perception questionnaire, digital photographs of global pictures head crown
Visit 06: [Day 135 (±2 days)]	Hair length (Affected targeted area and standard area), hair thickness, hair density, scalp condition for keratin measurement, hair regrowth (Affected area), number of hair fall from root, number of new hair (on head crown and normal scalp- tattoo area), hair root strength from root, general appearance of hair, general appearance of scalp, product perception questionnaire, digital photographs of global pictures head crown
Visit 07: [Day 177 (±2 days)]	Site marking, hair growth measurement.
Visit 08: [Day 180 (03 days from Visit 07)]	Hair growth rate measurement, hair length (standard area and Androgenic Alopecia affected targeted area), hair thickness, hair density, scalp condition for keratin measurement, A: T Ratio, number of new hair (on head crown, AG affected area), hair regrowth (AG affected area), number of hair fall from root, hair root strength, general appearance of hair, general appearance of scalp, product perception questionnaire, global pictures of head crown CBC, Biochemical tests, free testosterone, testosterone, dihydrotestosterone, CRP, Cortisol random, ferritin, urinalysis

mesh sieve to ensure uniformity. The final batches that met the predefined quality specifications were then packed in low-density polyethylene (LDPE) bags for dispatch. The liposomal Sesbania grandiflora leaf extract formulation demonstrated an entrapment efficiency of 69.95%, along with sustained release behavior and successful liposomal coating observed through SEM-EDX analysis, collectively supporting the successful formation and stability-related performance of the formulation.

Eligibility Criteria

This study included both male and female adults aged 25–45 years at the time of informed consent. Female participants were required to be non-pregnant and non-lactating; those of childbearing potential had a negative urine pregnancy test result at screening and were required to use an established method of contraception throughout the study period. All enrolled subjects were in good general health, as determined by the investigator based on their medical histories. Eligible subjects had mild to moderate androgenetic alopecia, classified as Grade I–III in males using the Norwood–Hamilton scale and in females using the Ludwig pattern scale. At screening, female subjects had a hair fall count of 40–50 hairs, whereas male subjects had 25–30 hairs. The subjects were either not receiving hormonal therapy or were on stable contraceptive or hormone replacement regimens for at least six weeks prior to enrolment, and agreed to maintain the same throughout the study. All subjects provided written informed consent, agreed to comply with the study procedures, and were willing to abstain from the use of medicated shampoos, minoxidil-containing products, hair growth treatments,

and hair dyes during the study duration. The participants also agreed to consume the investigational product as directed and attended all scheduled study visits.

Subjects were excluded if they had severe hair falls secondary to clinically significant systemic conditions, including anemia or thyroid disorders. Individuals with dermatological scalp diseases other than hair loss, dandruff, irritated, visibly inflamed, or severely diseased scalp were excluded. Subjects with a history of hair growth procedures including hair transplantation or laser therapy were excluded. The use of topical hair loss treatments within four weeks or systemic hair loss therapies within three months prior to screening was not permitted. Subjects with a history of alcohol or drug abuse or chronic medical conditions likely to affect the skin or hair physiology were excluded. Pregnant or lactating women as well as women planning pregnancy during the study period were not enrolled. Individuals currently participating in or planning to initiate weight loss programs likely to result in significant changes in body weight were excluded. Participants who had previously participated in clinical studies involving hair care products were not eligible. Subjects with a history of mastectomy involving lymph node removal within the past year or those who had received treatment for any malignancy within the previous six months were excluded.

Androgenic Alopecia Grading and Site Marking

Before the start of the study, the inter-subject reliability of hair loss grading was evaluated, and the grading system was validated for the consistency and reproducibility of clinical assessments. Hair loss grading was performed using the Norwood–Hamilton scale for males and the Ludwig scale for females by a dermatologist's trained staff and confirmed by a dermatologist.[13]

Hair measurements were performed at a single predefined scalp site to ensure the measurement accuracy and reproducibility. A small area on the vertex of the scalp was shaved, and a 1 cm^2 area was marked using medical-grade ink, which was used for the entire study. All subsequent measurements of hair growth parameters were conducted at the same site using phototrichogram analysis, enabling consistent, standardized, and reliable longitudinal assessments across study visits.[14]

Evaluation Parameters

CASLite Nova (Catseye Technology, Mumbai, India; DinoCapture 2.0) was used to measure the thickness and density of hair in both the affected and non-affected areas. Terminal and vellus hairs were recorded using the phototrichogram technique at 60× magnification to determine the hair density (hairs/cm^2). The shaft diameter of at least three hairs was measured, and the mean value was used for analysis. Hair thickness was evaluated in micrometres.[14]

At 60× magnification, a CASLite Nova Hair Analyzer was used to measure hair growth rate using the phototrichogram technique. Images of the shaved, marked area were taken on days 1 and 4, and three randomly chosen hairs were analyzed to determine the daily hair growth rate (μm/day) from the change in length over the 3-day interval.[14]

Anagen–telogen hair analysis was performed by gently plucking a lock of up to 30 hairs from the scalp using forceps protected with rubber, as close to the scalp surface as possible, to ensure the inclusion of miniaturized hairs and reduce breakage. The hair was then mounted on a glass slide using a transparent adhesive tape and examined under a light microscope at 40× magnification. Individual hairs were classified and recorded as either anagen or telogen.[14]

Hair fall was evaluated by asking the subjects to lean forward and comb their hair for 60 seconds on a colored sheet. The combination was performed in a predetermined manner from the occipital area to the top of the head and then to the frontal area. The hairs collected in the comb/brush and on the sheet were counted by the evaluator and categorized based on the presence or absence of a hair bulb, and the total hair count was recorded.[15]

Hair strength was evaluated using the hair pull test, a semiquantitative test of hair shedding. Approximately 60 hairs were gently grasped close to the scalp and pulled with equal force, and the number of hairs pulled out was recorded. Results were classified as negative (0–3 hairs), slightly positive (4–6 hairs), or clearly positive (>6 hairs, >10% of the tested hair).[15]

Hair keratin content was measured by the Bradford assay, a validated protein estimation method, with 0.05 g of hair samples analyzed for keratin content. The scalp condition was evaluated using CASLite Nova.[13]

The tensile strength of hair was measured using a calibrated TESTRONIX Tensile Hair Tester (Model TX TST (C)). Clean and dry hair samples (approximately 15 cm long) were placed in the tester and force was applied gradually until the hair broke. The tensile strength of the hair was determined as the maximum force at break divided by the cross-sectional area of the hair, and was measured in g/m^2. (Figure 1). [16]

The general appearance of hair and scalp was assessed by a dermatologist and a trained clinical evaluator using a standardized clinical grading system. Hair parameters, including volume, density, plasticity, shininess, smoothness, oiliness, dryness, and strength, along with scalp characteristics such as itchiness, dryness, redness, roughness, and scaliness, were evaluated to provide a comprehensive assessment of overall hair and scalp health.[14]

Hair length was assessed using two methods based on region. In androgenetic alopecia–affected areas, hair length was measured in micrometers using the phototrichogram technique, whereas in standardized areas with longer hair, measurements were obtained in centimeters using a calibrated ruler. The standard site was marked 15 cm from the nasal tip toward the scalp vertex, and the hair strands were gently extended downward for length measurements.[13]

Hair Regrowth (baby hair from the bald scalp) was evaluated using CASLite Nova in the affected area.[11] Hair counts were analyzed using the CASLite Nova phototrichogram and Image-Pro software (Media Cybernetics).

Nail Evaluation

Nail Brittleness was assessed using physician global assessment scoring system.

Randomization and Blinding

Subjects were randomized in a 1:1 ratio to receive either the plant-based liposomal capsule or the placebo capsule. The randomization sequence was generated by an independent biostatistician using R Software (Version 4.3.1, 64-bit), To ensure a double-blind design, all products were identically packaged, and both subjects and outcome assessors were blinded to group assignments. The study staff responsible solely for product dispensing was not involved in other study procedures, minimizing the risk of unblinding. Block randomization was used and a central computer system implemented a random allocation sequence. All randomization and statistical procedures were conducted using R Software (R Core Team, 2023, Vienna, Austria).

Statistical Analysis

All data were reviewed prior to analysis to ensure accuracy and completeness. Records with missing data were also excluded. Descriptive statistics (N, Mean, SD, Median, Minimum, and Maximum) were used to summarize the continuous variables. Categorical data were expressed in terms of frequency and percentage, and graphs were used when needed. A paired *t*-test was used to compare continuous variables from baseline to posttreatment. For Ordinal variables, the Wilcoxon signed-rank test was used for comparisons between baseline and posttreatment.

Figure 1 (**a**) represent standardization of evaluation sites for consistent measurement of hair growth rate, hair density, hair thickness, and scalp condition across study visits, (**b**) represent clinical assessment parameters including hair growth rate, hair density, hair thickness, and scalp condition, (**c**) represent assessment of hair shedding using standardized collection and evaluation procedures to quantify reduction in hair fall during the study period, (**d**) represent evaluation of hair fiber strength using controlled mechanical force to determine resistance to breakage and improvement in hair structural integrity.

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For comparisons between treatments, either an independent *t*-test or the Mann–Whitney *U*-test was used. Adverse events (AEs) were expressed in terms of frequency and percentage.

Statistical analyses were performed using IBM SPSS Statistics for Windows, Version 29.0.1.0 (2023; IBM Corp., Armonk, NY, USA) and Microsoft Excel 2019 (Microsoft Corp., Redmond, WA, USA). A significance level of 5% was used.

Sample Size Calculation

The sample size for this study was determined to ensure adequate statistical power for detecting clinically meaningful changes in hair growth and density. Using R Software, a paired *t*-test was applied with a significance level (α) of 0.05, power (1–β) of 0.80, and expected effect size of 0.608, resulting in an estimated requirement of n = 18.16 evaluable subjects. To account for an expected 15% dropout rate per arm, 39 subjects were enrolled, of whom 35 completed the study. This ensured adequate sample size retention to provide reliable and scientifically valid outcomes across both the product groups.

Result

Subject Demographics and Baseline Characteristics

The study included 35 subjects, including 21 females and 14 males (mention in Table 2). Data analysis was conducted on a per protocol basis. (mention in Figure 2).

Primary Endpoint

Hair Thickness

In the non-affected area in the liposomal encapsulated formulation group, at baseline on day 01, the mean hair thickness was 12.24 ± 1.64µm, which increased to 13.41 ± 1.62µm ($p < 0.0001$) by day 45. On Day 90, it further increased to 14.75 ± 1.61µm ($p < 0.0001$), on Day 135, it further increased to 16.12 ± 1.62µm ($p < 0.0001$), on Day 180, it further increased to 17.82 ± 2.01µm ($p < 0.0001$). In the Placebo group, the mean hair thickness at baseline on Day 01, the mean hair thickness was 11.00 ± 1.64 µm, which increased to 11.17 ± 1.47µm ($p > 0.05$) by day 45. On Day 90, it increased to 11.33 ± 1.61µm ($p > 0.05$), on Day 135, it increased to 11.44 ± 1.98µm ($p > 0.05$), on Day 180, it further increased to 12.06 ± 1.51µm ($p < 0.001$). On Day 180, hair thickness was improved by 46.39% in the liposome-encapsulated formulation and 10.50% improvement in placebo group. On Day 180, in females, hair thickness was improved by 47.52% in liposomal

Table 2 Subject Demographic Details

Variables	Statistics	Liposomal Encapsulated Formulation (n=17)	Placebo (n=18)
Gender M / F / TG	**Female**	14 (82.35%)	7 (38.89%)
	Male	3 (17.65%)	11 (61.11%)
Predominant Race	**Asian**	17 (100.00%)	18 (100.00%)
Medical/ ConMed History (Yes/No)	**No**	17 (100.00%)	18 (100.00%)
Androgenic Alopecia Grade	**I**	13 (76.47%)	10 (55.56%)
	II	4 (23.53%)	7 (38.89%)
	III	0 (0.00%)	1 (5.56%)
Age (Yrs)	**Mean (SD)**	35.35 (5.50)	35.67 (5.22)
Weight (Kg)	**Mean (SD)**	65.35 (11.84)	64.46 (15.29)
Height (Cm)	**Mean (SD)**	153.94 (10.16)	161.39 (9.77)

Note: Data are presented as mean (SD). M, male; F, female; TG, transgender; SD, standard deviation.

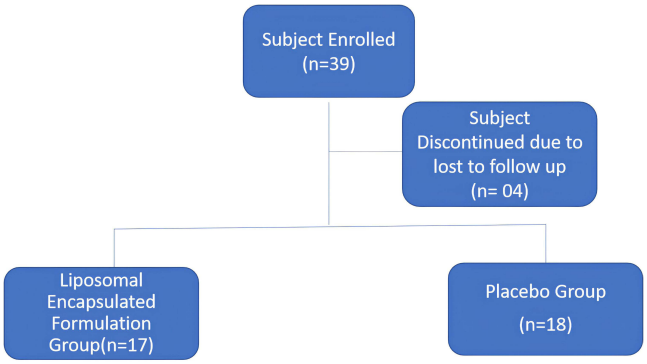

Figure 2 Flow diagram depicting participant enrolment and treatment allocation throughout the study period.

encapsulated formulation and 11.61% improvement in placebo group, which showed 4.94X fold improvement in liposomal encapsulated formulation with p <0.0001). In males, hair thickness was improved by 41.11% in the liposome-encapsulated formulation and 9.79% improvement in placebo group, which showed 5.33X time improvement in liposomal encapsulated formulation with p-value <0.05.

In Affected Area in liposomal encapsulated formulation group, at baseline on Day 01, the mean hair thickness was 5.53 ± 1.12µm, which increased to 6.35 ± 0.93µm (p <0.0001) by 45 days. On Day 90, it further increased to 7.25 ± 1.13µm (p <0.0001), on Day 135, it further increased to 8.35 ± 1.11 (p <0.0001), on Day 180, it further increased to 9.53 ± 1.28µm (p <0.0001). In the placebo group, the mean hair thickness at baseline on Day 01, the mean hair thickness was 5.72 ± 1.07µm, which increased to 5.89 ± 1.13 (p >0.05) by day 45. On Day 90, it further increased to 6.00 ± 1.19µm (p >0.05); on day 135, it same as baseline 6.39 ± 0.92µm (p <0.01), and on day 180, it increased to 6.44 ± 1.04µm (p <0.01). On Day 180, hair thickness was improved by 76.86% in the liposome-encapsulated formulation and 14.35% improvement in placebo group. On Day 180, in females, hair thickness was improved by 77.35% in liposomal encapsulated formulation and 10.82% improvement in placebo group, which showed 6.88X times improvement in liposomal encapsulated formulation with p <0.0001). In males, hair thickness was improved by 74.60% in the liposome-encapsulated formulation and 16.59% improvement in placebo group, which showed 5.30X time improvement in liposomal encapsulated formulation with p-value <0.001 (mentioned in Figure 3) (mentioned in Table 3).

Hair Density

In the non-affected area in the liposomal encapsulated formulation group, at baseline on day 01, the mean hair density was 254.94 ± 36.16Sqcm, which increased to 265.94 ± 36.21Sqcm (p <0.0001) by day 45. On Day 90, it further increased to 276.88 ± 34.31Sqcm (p <0.0001), on Day 135, it further increased to 291.18 ± 31.52Sqcm (p <0.0001), on Day 180, it further increased to 304.82 ± 28.46Sqcm (p <0.0001). In the Placebo group at baseline on Day 01, the mean hair density was 238.72 ± 31.19Sqcm, which increased to 240.33 ± 29.09Sqcm (p >0.05) by day 45. On Day 90, it further increased to 241.78 ± 29.05Sqcm (p >0.05), on Day 135, it further increased to 244.94 ± 31.47Sqcm (p <0.05), on Day

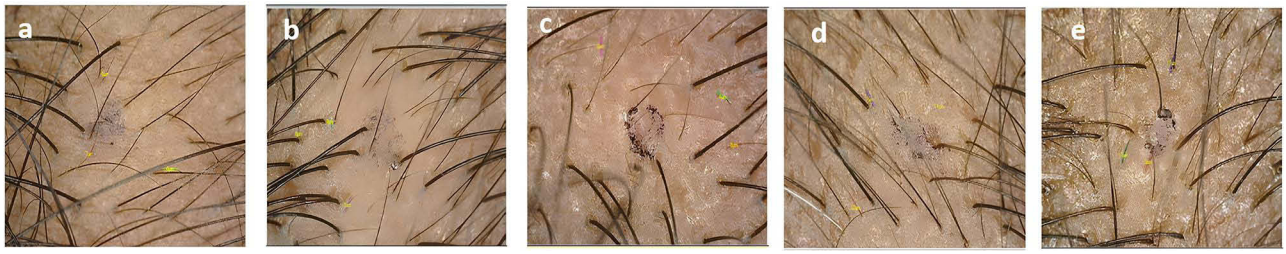

Figure 3 Presents representative images illustrating progressive changes in hair thickness (µm) in Sub# 37 over the study period. At Day 01 in (**a**), baseline hair thickness was recorded as 07 µm, which showed a gradual increase over time. At Day 45 in (**b**), hair thickness increased to 08 µm, followed by 09 µm at Day 90 in (**c**). Further progression was observed at Day 135 in (**d**), where hair thickness reached 10 µm, and by Day 180 in (**e**), the hair thickness further increased to 11 µm.

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Table 3 Comparative Percentage Change From Baseline (%CFB) in Hair Parameters

Variables	Visit Day	Liposomal Encapsulated Formulation	Placebo	Liposomal Encapsulated Formulation	Placebo
		Non-Affected Area		Affected Area	
Hair Density	Day 45	4.42% ↑	0.86% ↑	4.28% ↑	1.21%↑
	Day 90	9.23% ↑	1.50% ↑	9.31% ↑	1.78%↑
	Day 135	14.79% ↑	2.78% ↑	13.92% ↑	2.34%↑
	Day 180	20.52% ↑	2.86% ↑	20.31% ↑	2.59%↑
Hair Thickness	Day 45	9.91% ↑	1.93% ↑	16.62% ↑	3.24%↑
	Day 90	21.03% ↑	3.38% ↑	35.24% ↑	5.74%↑
	Day 135	32.57% ↑	3.96% ↑	54.52% ↑	13.47%↑
	Day 180	46.39% ↑	10.50% ↑	76.86% ↑	14.35%↑
Hair Length	Day 45	7.72% ↑	4.32% ↑	3.87% ↑	1.02%↑
	Day 90	14.19% ↑	7.19% ↑	15.04% ↑	2.04%↑
	Day 135	23.00% ↑	8.29% ↑	22.72% ↑	2.66%↑
	Day 180	34.56% ↑	12.67% ↑	34.25% ↑	4.75%↑

Note: ↑ indicates an increase compared with baseline values.

180, it increased from baseline to 244.17 ± 27.32Sqcm ($p > 0.05$). On Day 180, hair density was improved by 20.52% in the liposome-encapsulated formulation and 2.86% improvement in placebo group. Further In sub-group analysis, on day 180, in females, hair density was improved by 20.08% in liposomal encapsulated formulation and 5.40% improvement in placebo group, which showed 4.52X time improvement in liposomal encapsulated formulation with p-value <0.001. In males, hair density was improved by 22.56% in liposomal encapsulated formulation and 1.24% improvement in placebo group, which showed 26.83X fold improvement in liposomal encapsulated formulation with $p < 0.01$).

In Affected Area in liposomal encapsulated formulation group, at baseline on Day 01, the mean hair density was 229.65 ± 29.47Sqcm, which increased to 239.06 ± 27.30Sqcm ($p < 0.0001$) by 45 days. On Day 90, it further increased to 250.44 ± 26.66Sqcm ($p < 0.0001$), on Day 135, it further increased to 260.94 ± 28.40Sqcm ($p < 0.0001$), on Day 180, it further increased to 274.88 ± 25.05Sqcm ($p < 0.0001$). In the placebo group, at baseline on Day 01, the mean hair density was 207.89 ± 51.16Sqcm, which increased to 209.56 ± 50.48Sqcm ($p > 0.05$) by day 45. On Day 90, it further increased to 210.61 ± 50.32 ($p > 0.05$), on Day 135, it same as baseline 211.67 ± 50.53Sqcm ($p > 0.05$), on Day 180, it further increased to 212.17 ± 51.08Sqcm ($p > 0.05$). On Day 180, hair density was improved by 20.31% in the liposome-encapsulated formulation and 2.59% improvement in placebo group. On Day 180, in females, hair density was improved by 19.16% in liposomal encapsulated formulation and 2.81% improvement in placebo group, which showed 6.52X times improvement in liposomal encapsulated formulation with $p < 0.001$). In males, hair density was improved by 25.70% in the liposome-encapsulated formulation and 2.44% improvement in placebo group, which showed 19.99X time improvement in the liposome-encapsulated formulation with $p < 0.05$).(mention in Figure 4) (mention in Table 3).

Hair Growth Rate

In Non-Affected Area in liposomal encapsulated formulation group, at baseline on Day 01, the mean hair growth rate was 266.06 ± 61.29μm/day, which increased to 292.81 ± 60.22μm/day ($p < 0.01$) by 90 days. On Day 180, it further increased to 323.65 ± 61.38μm/day ($p < 0.0001$). In the Placebo group at baseline on Day 01, the mean hair growth rate was 275.67 ± 71.60μm/day, which increased to 278.83 ± 70.91μm/day ($p < 0.05$) by day 90. On Day 180, it increased to 283.61 ±

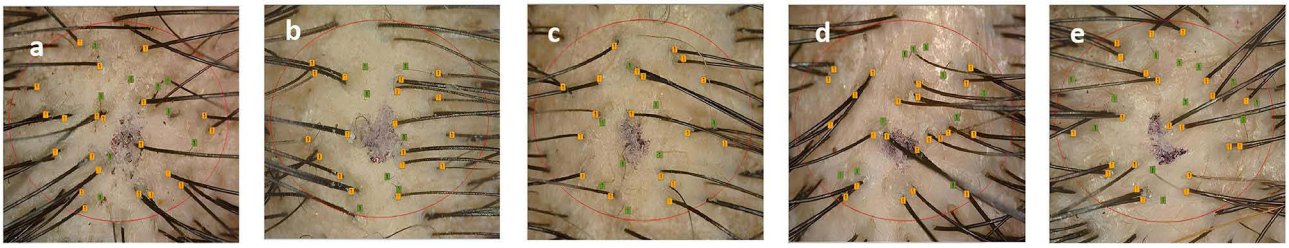

Figure 4 Presents representative images illustrating progressive changes in hair density (Sqcm) in Sub# 13 over the study period. At Day 01 in (**a**), baseline hair density was recorded as 227 Sqcm, which showed a gradual increase over time. At Day 45 in (**b**), hair density increased to 236 Sqcm, followed by 245 Sqcm at Day 90 in (**c**). Further progression was observed at Day 135 in (**d**), where hair density reached 255 Sqcm, and by Day 180 in (**e**), the hair density further increased to 273 Sqcm. The yellow numbered boxes indicate "TH" representing Terminal Hairs, the green numbered boxes indicate "Vh" representing Vellus Hairs, and the red circles denote the selected area used for calculation and analysis.

67.39µm/day ($p < 0.05$). On Day 180, hair growth rate was improved by 25.02% in the liposome-encapsulated formulation and 3.73% improvement in placebo group. (mention in Figure 5) (mention in Table 4).

Secondary Endpoint

Scalp Condition

In Non-Affected area of liposomal encapsulated formulation group, 100% subjects had dry scalps. Specifically, 58.82% subjects had dry scalp with some keratin, whereas the remaining 41.18% subjects had dry scalp with much keratin. On Day 180, a significant improvement was evident: 70.59% subjects had achieved a normal scalp condition with good hair density and thickness, while the remaining 29.41% subjects still had dry scalp with some keratin. In the placebo group, the majority of subjects had signs of scalp dryness. Specifically, 50% subjects had a dry scalp with much keratin, while 44.44% subjects had dry scalp with some keratin, and only 5.56% subject had a normal scalp condition. On Day 180, improvement in scalp condition was observed. 77.78% subjects still had a dry scalp with some keratin, but 22.22% subjects achieved a normal scalp with good hair density and thickness.

In Affected the in liposomal encapsulated formulation group, 100% subjects showed signs of a dry scalp. Specifically, 58.82% subjects had dry scalp with some keratin, whereas the remaining 41.18% subjects had dry scalp with much keratin. On Day 180, a significant improvement was observed; 58.82% subjects had achieved a normal scalp condition with good hair density and thickness, while the remaining 41.18% subjects still had dry scalp with some keratin. In the placebo group, scalp condition showed limited improvement over time. At Day 01, 61.11% subjects had a dry scalp with some keratin, 33.33% subjects had a dry scalp with high keratin, and only 5.56% subject had a normal scalp with good hair density and thickness. On Day 180, 66.67% subjects still had some keratin presence, while 33.33% subjects achieved a normal scalp with good hair density and thickness. (Figure 6), respectively.

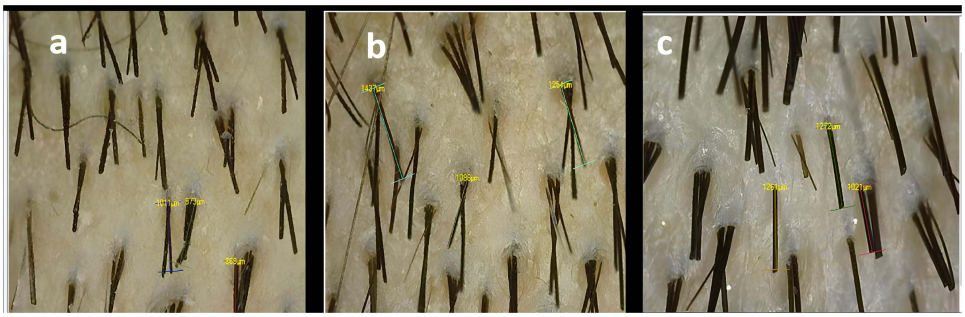

Figure 5 Presents representative images illustrating changes in hair growth rate (µm/day or mm/day) in Sub# 13 over the study period. At Day 01 in (**a**), baseline hair growth rate was recorded as 261 µm/day (0.261 mm/day). A slight increase was observed at Day 90 in (**b**), where the growth rate was 266 µm/day (0.266 mm/day). Further progression was observed at Day 180 in (**c**), where the hair growth rate increased to 347 µm/day (0.347 mm/day).

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Table 4 Percentage Change From Baseline (%CFB) in Key Hair Growth and Hair Fall Parameters

Variables	Visit Day	Liposomal Encapsulated Formulation	Placebo
Total No. of Hairs Through CASLite Nova	Day 45	4.45% ↑	0.28% ↑
	Day 90	8.85% ↑	0.81% ↑
	Day 135	14.70% ↑	2.48% ↑
	Day 180	20.19% ↑	0.88% ↑
Total No. of Hairs Through Image-Pro Analysis	Day 45	3.55% ↑	1.07%↓
	Day 90	6.58% ↑	1.01%↓
	Day 135	10.20% ↑	0.76%↓
	Day 180	13.37% ↑	3.25%↑
Hair Regrowth	Day 45	17.13% ↑	0.00%
	Day 90	40.19% ↑	1.11% ↑
	Day 135	62.26% ↑	5.09% ↑
	Day 180	92.77% ↑	8.24% ↑
No. of Hair Fall without Hair Bulb	Day 45	17.14% ↓	3.77% ↓
	Day 90	26.51% ↓	1.12% ↓
	Day 135	44.11% ↓	0.51% ↓
	Day 180	63.17% ↓	1.84% ↓
No. of Hair Fall with Hair Bulb	Day 45	18.38% ↓	5.87% ↓
	Day 90	31.60% ↓	7.64% ↓
	Day 135	44.91% ↓	10.49% ↓
	Day 180	67.17% ↓	13.89% ↓
Total No. of Hair Fall	Day 45	17.94% ↓	5.57% ↓
	Day 90	29.77% ↓	5.07% ↓
	Day 135	45.46% ↓	6.57% ↓
	Day 180	65.89% ↓	7.17% ↓
Hair Growth Rate	Day 90	12.00% ↑	1.34% ↑
	Day 180	25.02% ↑	3.73% ↑
Tensile Strength	Day 180	17.05% ↑	3.18% ↓

Note: ↑ indicates an increase compared with baseline values ↓ indicates a decrease compared with baseline values.

Keratin Measurement

In liposomal encapsulated formulation group, at baseline on Day 01, the mean keratin was 52.55 ± 26.01, which increased to 56.72 ± 26.29 ($p > 0.05$) by 180 days. In the placebo group, the mean keratin was 75.79 ± 15.15, which decreased to 71.82 ± 21.25 ($p > 0.05$). On Day 180, keratin was improved by 43.77% in the liposome-encapsulated formulation and 4.64% reduction in placebo group. (Figure 7).

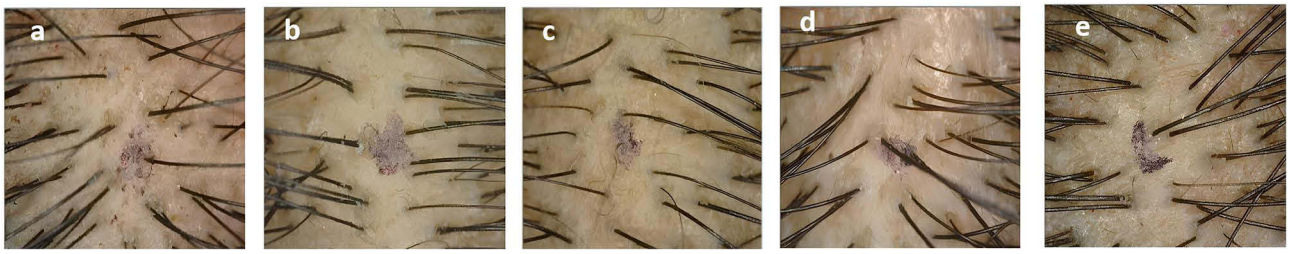

Figure 6 Presents representative images illustrating progressive changes in scalp condition in Sub# 13 over the study period. At Day 01 in (**a**), the scalp was observed to be dry with much keratin. At Day 45 in (**b**), the scalp condition showed slight improvement, with dry scalp with some keratin. Similar observations were recorded at Day 90 in (**c**) and Day 135 in (**d**), where the scalp remained dry with some keratin. By Day 180 in (**e**), the scalp condition improved, showing a normal scalp with good hair density and thickness.

Figure 7 Presents representative images illustrating changes in hair keratin levels in the Liposomal Encapsulated Formulation group and Placebo group before and after product usage. (**a**) shows Sub# 47 before product usage in the Liposomal Encapsulated Formulation group, while (**b**) shows Sub# 47 after product usage. (**c**) shows Sub# 12 before product usage in the Placebo group, and (**d**) shows Sub# 12 after product usage.

Hair Length

In Non-Affected area in the liposomal encapsulated formulation group, at baseline on day 01, the mean hair length was 18.94 ± 18.65cm, which increased to 19.95 ± 18.62cm ($p < 0.0001$) by day 45. On Day 90, it further increased to 21.34 ± 19.19cm ($p < 0.0001$), on Day 135, it further increased to 22.08 ± 19.29cm ($p < 0.0001$), on Day 180, it further increased to 23.89 ± 21.38cm ($p < 0.0001$). In the Placebo group at baseline on Day 01, the mean hair length was 10.01 ± 3.66cm, which increased to 10.37 ± 3.67cm ($p < 0.01$) by day 45. On Day 90, it further increased to 10.62 ± 3.67cm ($p < 0.0001$), on Day 135, it further increased to 10.77 ± 4.09cm ($p < 0.05$), on Day 180, it increased to 11.20± 4.05cm ($p < 0.0001$). On Day 180, hair length was improved by 34.56% in the liposome-encapsulated formulation and 12.67% improvement in placebo group.

In the Affected Area in the liposomal encapsulated formulation group, at baseline on day 01, the mean hair length was 174.65 ± 51.11µm, which increased to 180.88 ± 50.71µm ($p < 0.01$) by 45 days. On Day 90, it further increased to 199.75 ± 45.07µm ($p < 0.001$), on Day 135, it further increased to 209.53 ± 42.02µm ($p < 0.0001$), on Day 180, it further increased to 228.18 ± 43.71µm ($p < 0.0001$). In the placebo group at baseline on Day 01, the mean hair length was 182.28 ± 36.22µm, which increased to 184.06 ± 36.35µm ($p < 0.001$) by 45 days. On Day 90, it increased to 185.83 ± 36.22µm ($p < 0.0001$), on Day 135, it same as baseline 187.00 ± 36.60µm ($p < 0.0001$), on Day 180, it increased from baseline to 190.28 ± 36.22µm ($p < 0.001$). On Day 180, hair length was improved by 34.25% in the liposome-encapsulated formulation and 4.75% improvement in placebo group (mention in Table 3).

Total No. of Hairs – CASLite Nova

The total number of hairs in an area of 0.10613 cm^2 was evaluated using CASLite Nova. In liposomal encapsulated formulation group, at baseline on Day 01, the mean total number of hairs was 27.06 ± 3.83, which increased to 28.24 ± 3.85 by 45 days ($p < 0.0001$). On Day 90, it further increased to 29.31 ± 3.81 ($p < 0.0001$). On Day 135, it further increased to 30.88 ± 3.35 ($p < 0.0001$). On Day 180, it further increased to 32.29 ± 3.24 ($p < 0.0001$). In placebo group at baseline on Day 01, the mean total number of hairs was 25.33 ± 3.31, which increased to 25.39 ± 3.22 ($p > 0.05$) on Day 45. On Day 90, it increased from baseline to 25.50 ± 3.19 ($p > 0.05$). On Day 135, the mean was increased from baseline to 25.94 ± 3.37 ($p < 0.01$). On Day 180, the mean was increased from baseline to 25.50 ± 3.31 ($p > 0.05$). On Day 180, total No. of hairs were improved by 20.19% in liposomal encapsulated formulation and 0.88% improvement in placebo group. In females, on Day 180, the total number of No. of hairs was improved by 20.01% in liposomal encapsulated formulation and 3.19% improvement in placebo group, which showed 7.30X time improvement in liposomal encapsulated formulation with p-value <0.0001. In males, total No. of hair was improved by 21.04% in liposomal encapsulated formulation and 0.59% reduction in placebo group, which showed 29.33X time improvement in liposomal encapsulated formulation with p-value <0.05 (mention in Table 4).

Total No. of Hairs – Image-Pro Analysis

The total number of hair strands in the crown, mid, and frontal regions of the head was quantified. In liposomal encapsulated formulation group, at baseline on Day 01, the mean total number of hairs was 71384.12 ± 15,335.24, which increased to 73772.12 ± 15,206.35 by 45 days ($p < 0.0001$). On Day 90, it increased to 75426.63 ± 15,321.21 ($p < 0.0001$). On Day 135, it further increased to 78210.12 ± 14,807.62 ($p < 0.0001$). On Day 180, it further increased to 80367.06 ± 14,891.90 ($p < 0.0001$). Total of 8982.94 new hairs were observed in the head crown. In the placebo group at baseline on day 01, the mean total number of hairs was 60894.67 ± 19,169.05, which decreased to 60345.78 ± 19,309.64 ($p < 0.05$) on day 45. On Day 90, it decreased from baseline to 60374.00 ± 19,279.28 ($p < 0.05$). On Day 135, the mean was decreased from baseline to 60572.83 ± 19,312.07 ($p > 0.05$). On Day 180, the mean increased from baseline to 62991.39 ± 21,369.12 ($p > 0.05$). Total of 2096.72 new hairs were observed. On Day 180, total No. of hairs were increased by 13.37% in the liposomal-encapsulated formulation and 3.25% improvement in placebo group (mention in Table 4).

Anagen-Telogen Hairs

In the liposomal encapsulated formulation group, at baseline on Day 01, the mean percentage of % anagen hairs was 30.73 ± 12.22, which increased to 44.64 ± 14.18 ($p < 0.001$) by day 90. On Day 180, it further increased to 61.04 ± 12.44 ($p < 0.0001$). At baseline on Day 01, the mean percentage of % telogen hairs was 69.27 ± 12.22, which decreased to 55.36 ± 14.18 ($p < 0.001$) by day 90. On Day 180, it further decreased to 38.96 ± 12.44 ($p < 0.0001$). In the placebo group, at baseline on Day 01, the mean percentage of % anagen hairs was 32.78 ± 13.17, which increased to 35.02 ± 12.79 ($p > 0.05$) by 90 days. On Day 180, it further increased to 36.68 ± 11.21 ($p > 0.05$). At baseline on day 01, the mean percentage of % telogen hairs was 67.22 ± 13.17, which decreased to 64.98 ± 12.79 ($p > 0.05$) by 90 days. On Day 180, it further decreased to 63.32 ± 11.21 ($p > 0.05$) respectively (mention in Figures 8 and 9).

60 Seconds Hair Comb Test

Hair Fall Without Hair Bulb

In liposomal encapsulated formulation group at baseline on Day −04, the mean hair fall without hair bulb was 32.88 ± 14.21, which significantly decreased to 27.29 ± 12.83 ($p < 0.01$) by Day 45. On Day 90, it further decreased to 25.06 ± 12.62 ($p < 0.001$) on Day 135, further decreased to 18.47 ± 9.41 ($p < 0.0001$). On Day 180, it further decreased to 11.82 ± 7.17 ($p < 0.0001$). In placebo group at baseline on Day −04, the mean hair fall without hair bulb was 25.72 ± 8.40, which decreased to 24.39 ± 7.28 ($p > 0.05$) on Day 45. On Day 90, the mean hair fall decreased from baseline to 25.06 ± 8.77 ($p > 0.05$). By Day 135, the mean hair fall had decreased from baseline to 25.44 ± 9.79 ($p > 0.05$). On Day 180, it decreased from baseline to 25.67 ± 9.06 ($p > 0.05$). On Day 180, hair fall without hair bulb was reduced by 63.17% in liposomal encapsulated formulation and 1.84% reduction in placebo group (mention in Table 4).

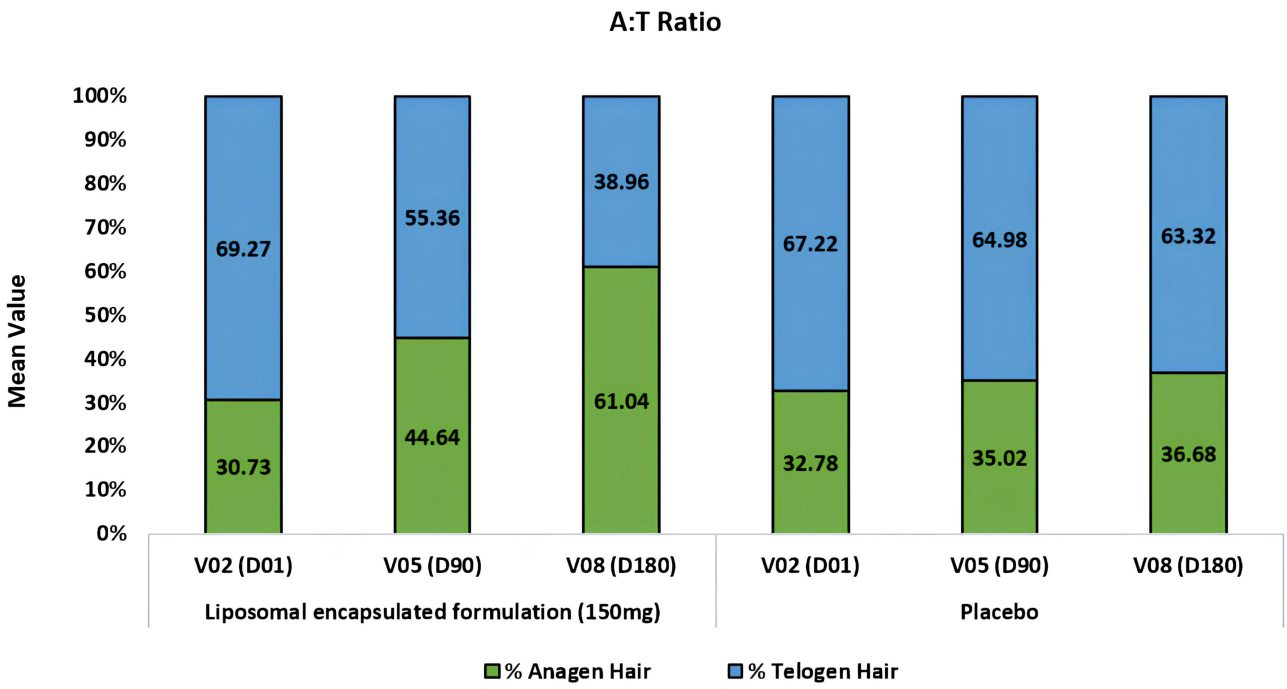

Figure 8 Change in percentage of anagen–telogen hairs across study groups over the study period. Data represent the variation in the proportion of hairs in the anagen and telogen phases following treatment.

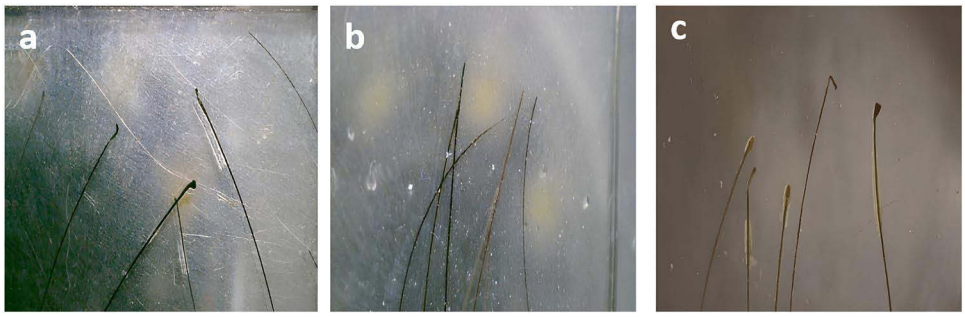

Figure 9 Presents representative images illustrating the anagen-to-telogen hair ratio in Sub# 37 across the study period. At baseline in (**a**), the anagen:telogen ratio was recorded as 16.67:83.33, indicating a predominance of telogen phase hairs. At the intermediate time point in (**b**), the ratio improved to 57.14:42.86, reflecting a shift towards increased anagen phase hair proportion. At the final time point (**c**), the ratio further improved to 80.00:20.00, indicating a marked increase in anagen phase hair.

Hair Fall With Hair Bulb

In the liposomal encapsulated formulation group at baseline on Day −04, the mean hair fall with the hair bulb was 37.65 ± 16.01, which decreased to 30.88 ± 13.51 ($p < 0.0001$) by day 45. On Day 90, it further decreased to 26.00 ± 10.80 ($p < 0.0001$), on Day 135, the hair fall further decreased to 20.53 ± 9.12 ($p < 0.0001$). On Day 180, it further decreased to 12.41 ± 7.47 ($p < 0.0001$). In the placebo group at baseline on Day −04, the mean hair fall with the hair bulb was 30.72 ± 17.86, which decreased to 28.56 ± 17.66 ($p > 0.05$) on day 45. On Day 90, the mean hair loss decreased to 27.94 ± 17.81 ($p > 0.05$) in hair fall. By Day 135, the mean hair loss decreased to 27.28 ± 17.35 ($p < 0.05$) in hair fall. On Day 180, it decreased to 26.61 ± 18.18 ($p < 0.05$). On Day 180, hair fall with hair bulb was reduced by 67.17% in liposomal encapsulated formulation and 13.89% reduction in placebo group (mention in Table 4).

Total No. of Hair Fall

In the liposomal encapsulated formulation group at baseline on Day −04, the mean hair fall with the hair bulb was 70.53 ± 27.88, which significantly decreased to 58.18 ± 24.38 ($p < 0.0001$) by Day 45. On Day 90, it further decreased to 51.06

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± 22.11 (p <0.0001), on Day 135, the hair fall further decreased to 39.00 ± 17.15 (p <0.0001). On Day 180, it further decreased to 24.24 ± 13.56 (p <0.0001). In the placebo group at baseline on Day −04, the mean hair fall with the hair bulb was 56.44 ± 21.80, which decreased to 52.94 ± 20.73 (p <0.05) on day 45. On Day 90, the mean hair fall decreased from baseline to 53.00 ± 20.54 (p >0.05). By Day 135, the mean hair fall decreased to 52.72 ± 21.67 (p >0.05). On Day 180, it decreased to 52.28 ± 21.74 (p >0.05). On Day 180, total No. of hair fall was reduced by 65.89% in liposomal encapsulated formulation and 7.17% reduction in placebo group (mention in Table 4).

Hair Regrowth

In the liposomal-encapsulated formulation group, the mean hair regrowth rate was 5.53 ± 2.07. On Day 45, it increased to 6.35 ± 1.97 (p <0.0001). On Day 90, hair regrowth further increased to 7.63 ± 2.09 (p <0.0001). On Day 135, it increased to 8.53 ± 2.03 (p <0.0001). On Day 180, the mean hair regrowth was 10.06 ± 1.98 (p <0.0001). In the placebo group at baseline on Day 01, the mean hair regrowth rate was 5.56 ± 2.15. On Day 45, these values remained the same. On Day 90, the mean hair regrowth was 5.61 ± 2.15 (p >0.05). On Day 135, the mean hair regrowth increased to 5.72 ± 2.11 (p >0.05). On Day 180, it increased to 5.89 ± 2.05 (p <0.01). On Day 180, hair regrowth was improved by 92.77% in the liposome-encapsulated formulation and 8.24% improvement in placebo group (mention in Table 4).

Hair Tensile Strength

In the liposomal encapsulated formulation group, the mean tensile strength was 30219.63 ± 6232.58gm/cm², which significantly increased to 35086.09 ± 6374.81gm/cm² (p <0.0001) on Day 180. In the placebo group, the mean tensile strength was 30679.40 ± 10,218.50gm/cm², which decreased to 29692.47 ± 10,061.67gm/cm² (p <0.05). On Day 180, hair tensile strength was improved by 17.05% in liposomal encapsulated formulation and 3.18% reduction in placebo group (mention in Table 4). On Day 180, in females, hair tensile strength was improved by 17.03% in liposomal encapsulated formulation and 1.03% reduction in placebo group, which showed 10.25X times improvement in liposomal encapsulated formulation with p-value <0.001. In males, hair tensile strength was improved by 17.18% in liposomal encapsulated formulation and 4.55% reduction in placebo group, which showed 4.50X times improvement in liposomal encapsulated formulation with p-value <0.001.

Hair Root Strength

In liposomal encapsulated formulation group, 70.59% of subjects had poor hair strength, and 29.41% had average hair strength at baseline. On day 180, 5.88% had average and 94.12% had good strength. In placebo group, 88.89% of subjects had poor and 11.11% had average hair strength at baseline; on day 180, 50% had poor, 44.44% had average, and 5.56% had good hair strength.

General Appearance of Hair and Scalp

At the end of the study, hair volume, density, dryness, shininess, smoothness, and strength were compared to those in the placebo group. There were no cases of itchiness, redness, scaliness, dryness, or roughness in the liposomal capsule, whereas placebo had some cases.

Subject Perception Questionnaire

100% subjects did not experience any irritation reactions such as redness, dryness, itchiness, burning, sensation etc. of the scalps upon usage of products. 100% subjects felt that hair becomes soft, silky, and shiny after usage of products. 100% subjects felt that test products were effective in improving hair thickness and density. 100% subjects felt that the products effectively produced visible baby hair on scalp after usage. 100% subjects felt that the products were effective in reducing hair fall after product usage. In liposomal encapsulated formulation group, 100% subjects felt that the test product is effectively provided a healthier looking hair scalp after product usage; however in placebo group, 94.44% subjects felt that the test product is effectively provided a healthier looking hair scalp after product usage, and 5.56% had felt no effect. 100% subjects felt that The test product is effectively improved nail brittleness. 100% subjects satisfied with the use of test product.

Table 5 Adverse Events (AEs)

Adverse Events	Count	Percentage
Liposomal encapsulated formulation		
Fever	1	5.88%
No AE	16	94.11%
Placebo		
Body Ache	3	16.67%
Acidity	1	5.56%
Fever and body pain	1	5.56%
Cough	1	5.56%
No AE	12	66.65%

Nail Brittleness

In the liposome-encapsulated formulation group, at nail#1, at baseline, 5.88% of subjects had mild brittleness, 64.71% of subjects had mild to moderate brittleness, and 29.41% of subjects had moderate brittleness. By Day 180, 35.29% of subjects had no brittleness, 41.18% of subjects improved to mild, and 23.53% of subjects remained mild to moderate. Moderate cases dropped to zero. In placebo group, at baseline, 5.56% of subjects had mild brittleness, 88.89% of subjects had mild to moderate brittleness, and 5.56% of subjects had moderate brittleness. On Day 180, 11.11% of subjects had mild brittleness, 83.33% of subjects remained mild to moderate, and 5.56% of subjects still had moderate brittleness. None of the patients achieved complete resolution of symptoms, indicating minimal improvement.

In liposomal encapsulated formulation group, at nail#2, initially, 11.76% subjects had mild brittleness, 82.35% subjects had mild to moderate brittleness, and 5.88% subjects had moderate brittleness. By Day 180, 35.29% subjects had no brittleness, 58.82% subjects improved to mild, and 5.88% subjects remained mild to moderate. All moderate cases resolved. In the placebo group, at baseline, 5.56% subjects had mild brittleness and 94.44% subjects had mild to moderate brittleness. By Day 180, the distribution remained unchanged 5.56% subjects mild, 94.44% subjects mild to moderate), indicating no improvement in nail brittleness.

Adverse Events

Overall, both products were well-tolerated throughout the study period, with no serious adverse events (SAEs) reported in either group. In the liposomal group, a single episode of fever was reported in 5.88% of subjects. This event was mild in intensity and assessed as unrelated to the liposomal encapsulated test product. No additional adverse events were reported in this group and the remaining participants (94.12%) completed the study without experiencing any adverse events.

Adverse events were reported more frequently in the placebo group. Body ache was observed in 16.67% of subjects, whereas acidity, fever accompanied by body pain, and cough were each reported in 5.56% of subjects. The majority of subjects in the placebo group (66.65%) did not report any adverse events. All adverse observed in the placebo group were mild and self-limiting. (mention in Table 5).

Lab Parameter

In the liposomal encapsulated formulation group, hematological parameters including Hb, Hct, RBC, MCH, MCV, and WBC, as well as biochemical parameters such as SGOT, SGPT, BUN, RBG, PPBS, TC, TG, HDL, - LDL, VLDL, CRP, Random Serum Cortisol, and Serum Ferritin, showed no statistically significant changes from baseline to the end of the study. A statistically significant change was observed in serum uric acid levels; however, the mean values remained

within the established normal reference ranges, indicating no clinical relevance. In addition, the MCHC demonstrated a statistically significant change. Random serum cortisol was reduced by 7.45% and ferritin was improved by 32.69%.

In the placebo group, hematological and biochemical parameters, including Hb, Hct, RBC, MCH, MCV, MCHC, SGOT, SGPT, serum creatinine, BUN, RBG, PPBS, TC, TG, HDL, LDL, VLDL, Uric acid, CRP, random cortisol, and ferritin showed no statistically significant changes during the study period. A statistically significant change was observed in the WBC count; however, the values remained within the normal physiological limits. Random serum cortisol was reduced by 5.81% and ferritin was improved by 9.35%.

Assessment of hormonal parameters revealed that in the liposomal encapsulated formulation group, mean testosterone levels increased in both male and female subjects, whereas mean free testosterone and mean DHT levels decreased in both sexes over the 180-day study period. In the placebo group, mean testosterone levels increased, mean free testosterone increased in male subjects and decreased in female subjects, and mean DHT levels decreased in both males and females.

Safety Analysis

In the liposomal capsule and placebo groups, all the urine parameters were normal at the end of the study.

Discussion

Alopecia represents a heterogeneous group of disorders characterized by partial or complete hair loss from the scalp or other body sites, and is associated with a substantial psychosocial and quality-of-life burden in both men and women. Only a few pharmacological agents have been approved for clinical use, limiting the therapeutic options for alopecia despite its high prevalence and growing clinical demand. Furthermore, conventional topical treatments are often accompanied by several limitations including adverse effects such as scalp irritation, poor follicular penetration, and low bioavailability at the target site.

Alopecia can be divided into two types: scarring and nonscarring. Scarring alopecia is associated with irreversible follicular damage and permanent hair loss, whereas non-scarring alopecia maintains the follicular structure, thus providing a potential for hair regrowth. Among non-scarring alopecias, androgenetic alopecia (AGA) is the most common condition, with a prevalence of 30–50% in men and almost 30% in middle-aged women worldwide.[17]

The pathophysiology of AGA is complex and includes the interplay between genetic susceptibility and the abnormal metabolism of androgens. The pathophysiological mechanism involves the enzymatic conversion of testosterone to dihydrotestosterone (DHT) by 5-α-reductase, along with the increased expression of androgen receptors and increased sensitivity of follicles to androgen stimulation. This leads to progressive miniaturization of terminal hair follicles, shortening of the anagen phase, relative prolongation of the telogen phase, and conversion of terminal hair into vellus-like hair. These changes are reflected in decreased hair density, decreased hair shaft diameter, increased hair shedding, and visible scalp exposure.[4,5] Currently, topical minoxidil is the only FDA-approved treatment for the management of AGA in both males and females, and oral finasteride is FDA-approved for male pattern hair loss. Although these agents have remained the mainstay in the management of AGA, their need for continuous administration, the possibility of adverse effects, and inconvenient administration have led to growing interest in exploring alternative approaches for the management of AGA.[6,18] In this context, plant-derived bioactives have gained considerable attention due to their efficacy and favorable safety profiles. Several botanicals, including *Acacia concinna, Camellia oleifera, Azadirachta indica, Emblica officinalis, Sapindus mukorossi, Garcinia mangostana, Eclipta alba, Allium cepa, Hibiscus rosa-sinensis, Lawsonia inermis* have long been utilized in traditional hair care formulations for hair growth, reduce dandruff and improve hair texture.[7,19] More recently, Sesbania grandiflora has emerged as a promising plant of interest due to its rich content of bioactive phytoconstituents, including biotin and polyphenolic compounds, which are associated with key roles in keratin synthesis, cellular energy metabolism, and antioxidant defense mechanisms. In the present study, this plant was selected and utilized as the active botanical source for evaluation of hair and scalp parameters.[8]

In the present study, the severity of androgenetic alopecia was determined using the Norwood–Hamilton classification for males and the Ludwig scale for females. The current study used validated and standardized procedures for hair and scalp evaluation, using both noninvasive and semi-invasive techniques. Objective assessments included hair density,

thickness, length, growth rate, and anagen-telogen hair, tensile strength, keratin levels, and hair fall. These procedures were previously standardized by NovoBliss Research Pvt. Ltd. These were selected to ensure reproducibility and robustness of the assessment of treatment-related changes in hair and scalp biology.[13–15] Previously study was conducted to trained evaluator for PGA scale for nail brittleness.[20]

This randomized, placebo-controlled, 180-day clinical study assessed the safety, efficacy, and tolerability of a liposomal formulation containing *Sesbania grandiflora* extract. The liposomal formulation showed progressive and statistically significant improvements across multiple primary and secondary endpoints, including hair density, thickness, hair regrowth, anagen-telogen hair, tensile strength, keratin level, reduction in hair fall, and improvement in scalp condition, whereas placebo showed relatively small changes. The hair growth rate shifted towards normalization in the liposomal group. The increase in testosterone levels with a concomitant decrease in DHT levels suggests the modulation of androgen metabolism rather than increased androgen production. Since DHT is produced from testosterone by 5-α-reductase, this pattern could indicate reduced conversion to DHT or decreased availability to follicles, potentially contributing to reduced androgenic signaling and improvement in hair growth parameters. Notably, the formulation was well tolerated with no clinically relevant safety concerns observed during the study period. Collectively, these results suggest that the liposomal liposomal *Sesbania grandiflora* formulation has a beneficial effect on both androgenetic alopecia-affected and-non-affected scalp regions, suggesting a generalized modulatory effect on hair follicle biology. The generalized effect of the formulation suggests its potential use not only in patterned hair loss but also in general hair shedding and non-pathological hair loss, thus supporting its use in improving overall hair growth, hair strength, and scalp health rather than just localized alopecia. The observed effect was attributed to the bioactive phytoconstituents of *Sesbania grandiflora*, specifically biotin and polyphenols. Biotin is essential for keratin synthesis, mitochondrial energy metabolism, and the maintenance of hair shaft structural integrity, whereas polyphenols exert antioxidant effects that mitigate oxidative stress, support scalp homeostasis, and protect follicular structures.[8,21,22]

In addition to the clinical results, mechanistic evidence for the potential effects of the formulation on hair biology was provided by prior in silico investigations of the standardized *Sesbania agati* leaf extract. Computational docking studies showed favorable interactions between the major bioactive compounds of the *Sesbania grandiflora* extract and molecular targets involved in hair follicle growth and differentiation, indicating a plausible mechanism by which these compounds may influence follicular function. The extract also satisfied Lipinski's Rule of Five and the ADMET criteria, suggesting favorable drug-likeness and biopharmaceutical properties. Chromatographic characterization confirmed the presence of approximately 0.5% biotin in the extract, and molecular docking predicted that biotin, in conjunction with additional cofactors, may activate pathways related to follicular activity and hair shaft formation, potentially providing enhanced biological activity over synthetic biotin alone.[8] In addition, in vitro and ex vivo studies of the extract have reported increased hair cell proliferation and activation of the Wnt/β-catenin signaling pathway, a major regulator of hair follicle cycling and regeneration.[9] Clinical evidence supports a role for biotin in hair biology. Previous studies have shown that biotin supplementation results in a marked increase in the anagen-to-telogen ratio,[23] whereas topical biotin formulations have shown improvements in hair strength and reduction in hair shedding with favorable cutaneous tolerability.[24] Previous clinical studies have shown that the standardized *Sesbania grandiflora* extract, administered for 56 days at a dose of 250 mg twice daily, containing 0.5% biotin, is safe, tolerable, and significantly improves in key hair growth parameters, such as hair density, hair thickness, and also ferritin level, in individuals presenting with thin, dry, and brittle hair and experiencing hair loss.[25] A recent report highlights the growing interest in plant-based serum as a potential breakthrough in hair loss management. Early clinical findings suggest that such serums may improve hair density and thickness within weeks, offering a promising alternative approach to conventional hair growth therapies while supporting the need for further large-scale validation studies. The formulation is reported to contain Centella asiatica- derived bioactive compounds, along with other plant-based cosmetic ingredients contributing to its proposed hair growth-promoting effects.[26] This 180-day randomized clinical study evaluated a reduced-dose liposomal formulation of *Sesbania grandiflora* for AGA to enhance the bioavailability and follicular delivery of its active constituents. Generally, liposomal encapsulation is employed to overcome the limitations of conventional non-liposomal extracts, such as poor solubility, gastrointestinal instability, limited cellular uptake, and variable absorption. By incorporating bioactive molecules into phospholipid bilayers, liposomes protect against degradation, improve dissolution, and facilitate

transmembrane transport, thereby enhancing absorption. This improved stability and bioavailability likely contributed to sustained systemic exposure and clinical efficacy at a lower dose. In overall, improvements across multiple hair and scalp parameters.[11,27]

A limitation of this study is that it had a single-center design, which may limit the generalizability of the results. Although the 180-day study duration was adequate for the evaluation of hair growth outcomes, long-term studies are required to assess the sustainability of the benefits and safety of this treatment. Moreover, the study did not involve a comparison with standard therapies such as minoxidil or finasteride. Future studies should incorporate larger multi-center designs with extended follow-up and comparative arms for further efficacy.

Conclusion

This randomized, double-blind, placebo-controlled clinical study demonstrated that the liposomal formulation of *Sesbania grandiflora*, a proprietary *Sesbania grandiflora* standardized to 0.5% biotin, is safe, well tolerated, and effective in individuals with hair fall in improving various objective and subjective parameters of hair and scalp health. During the 180-day intervention period, supplementation with liposomal *Sesbania grandiflora* led to significant improvements in hair density, thickness, growth rate, anagen-telogen hairs, hair regrowth, tensile strength, keratin content, and scalp condition, along with a consistent reduction in hair fall compared with placebo. The use of standardized and validated assessment methodologies and trained evaluators ensured the robustness and reproducibility of the findings. The clinical outcomes observed in this study are strongly supported by preclinical and computational evidence of the extract generated prior to clinical evaluation. The outcomes observed with the liposomal formulation suggest improved bioavailability and targeted delivery of biotin and associated phytoconstituents, supporting follicular activity and keratin synthesis. Collectively, the integration of preclinical, in silico, and clinical evidence supports liposomal *Sesbania grandiflora* as an effective intervention to improve hair and scalp health. These findings provide a strong foundation for further large-scale and long-term investigations and suggest that liposomal *Sesbania grandiflora* is a promising adjunct or alternative approach for the management of hair thinning and hair loss.

Abbreviation

AE, Adverse event; AGA, Androgenetic alopecia; androgen receptor (AR) gene; BUN, blood urea nitrogen; CDSCO, Central Drugs Standard Control Organization; CBC, complete blood count; DHT, Dihydrotestosterone; CRP, C-reactive protein; EDA2R, Ectodysplasin A2 receptor; FSFV, First subject first visit; GCP, good clinical practice; ICD, informed consent document; ICH, International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use; ICMR, Indian Council of Medical Research; IEC, institutional ethics committee/independent ethics committee; HDL, high-density lipoprotein; LDL, low-density lipoprotein; LDPE, low-density polyethylene; LLLT, low-level light therapy; LSLV, Last subject last visit PGA, physician global assessment; PPBS, post-prandial blood sugar; MCV, mean corpuscular volume; MCH, mean corpuscular hemoglobin concentration.; MCHC, mean corpuscular hemoglobin concentration; PRP, platelet-rich plasma; SAE, serious adverse event; SD, standard deviation; SOP, standard operating procedure; SGPT, serum glutamic-pyruvic transaminase; SGOT, serum glutamic-oxaloacetic transaminase; TC, total cholesterol; TG, triglycerides; VLDL, very-low-density lipoprotein cholesterol; RBC, red blood cells; RBG, random blood glucose; WBC, white blood cells.

Data Sharing Statement

Data supporting the findings of this study are available upon request from the corresponding author. The data were not publicly available due to privacy or ethical restrictions.

Ethics Approval and Informed Consent

This study was conducted according to all relevant SOP(s), study protocols, ICMR ethical guidelines, the International Council for Harmonization–Good Clinical Practice (ICH-GCP), and the Declaration of Helsinki. The study protocol (Ver#1.0) was approved by the ACEAS independent ethics committee on 20 Jul 2024, prior to commencement of the study procedures (Approval Number: NB240030-ZV). The study was registered with the Clinical Trial Registry of India

(CTRI) under registration# CTRI/2024/08/071884 and additionally listed on ClinicalTrials.gov with Identifier NCT06551818. All subjects provided written informed consent prior to enrolment.

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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The authors declare that they have no conflicts of interest related to this study. No financial, personal, or professional relationships influenced the research, analysis, or reporting of findings. Ratna Upadhyay has a patent pending on SesZenBio ingredient. Mr Mihir Gadani has a patent pending on SesZenBio ingredient.

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