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An Open-Label, Comparative Clinical Study to Evaluate the Efficacy and Safety of Narasimha Tablets in Adult Subjects with Hair Thinning and Hair Fall

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ABSTRACT

Background: Hair thinning and hair fall are widespread concerns affecting adults across age groups, with significant psychosocial implications. Current pharmacological treatments have limited efficacy and are associated with side effects, prompting a need for safe, herbal alternatives. **Objective:** To evaluate the efficacy and safety of Narasimha Tablets, a traditional Ayurvedic formulation, in promoting hair growth and reducing hair fall in adults experiencing hair thinning. **Methods:** This 6-month open-label, comparative clinical trial enrolled 100 participants aged 25–50 years presenting with self-reported hair thinning or hair fall. Subjects were randomized into two groups: 70 received Narasimha Tablets (2 tablets twice daily post-meals), and 30 received a placebo. Efficacy endpoints, including hair density, vellus hair count, hair fall, global investigator assessment, and self-rated hair thickness (VAS), were assessed at baseline, Day 90, and Day 180. Statistical analysis was conducted using paired t-tests and ANOVA. **Results:** The treatment group showed statistically significant improvements in all primary and secondary outcomes. Hair density increased from 145.2 ± 12.4 to 172.4 ± 14.2 hairs/cm² (+18.7%), vellus hair count increased by 28.2%, and daily hair fall reduced by 44.4% by Day 180. Subjective and investigator scores reflected parallel improvement, with the VAS score increasing by 92.8% and the global score by 82.6% ($p < 0.001$). **Conclusion:** Narasimha Tablets demonstrated significant efficacy in promoting hair growth, reducing hair fall, and improving overall hair quality, validating its role as a holistic, herbal intervention. Further randomized controlled trials are warranted to confirm these findings.

KEYWORDS: *Hair fall, Hair thinning, Narasimha Tablet, Ayurvedic formulation, Clinical trial, Herbal treatment*

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1. INTRODUCTION

Hair thinning and hair fall are common concerns among adult individuals, significantly affecting their quality of life and self-esteem. These conditions are often linked to various factors, including hormonal changes, stress, nutritional deficiencies, genetics, and environmental influences. While several over-the-counter treatments and prescription medications are available, many of these solutions offer limited effectiveness or come with adverse side effects, prompting a growing interest in alternative remedies.[1]

Narasimha tablets, an herbal formulation, have gained attention for their potential benefits in addressing hair thinning and hair fall. Derived from traditional Ayurvedic medicine, Narasimha tablets are believed to offer a combination of ingredients that promote hair growth, strengthen the hair follicles, and prevent hair loss. Despite evidence supporting the use of such remedies, there is a lack of well-controlled clinical trials to scientifically validate their efficacy and safety.

This study aims to fill this gap by conducting a randomized, double-blind, placebo-controlled clinical trial to evaluate the efficacy and safety of Narasimha tablets in adult subjects experiencing hair thinning and hair fall. The trial will assess various outcomes, including improvements in hair density, thickness, and overall scalp health, while also monitoring any potential adverse effects.

Hair loss is a multifactorial condition that can affect individuals of both genders across different age groups. In males, androgenetic alopecia is the most common form of hair loss, while in females, the causes can vary from hormonal imbalances to stress-related conditions. The global prevalence of hair thinning and hair fall has led to an increasing demand for effective treatments. [2]

Conventional treatments, such as minoxidil and finasteride, have shown varying levels of success. Minoxidil is a topical solution that stimulates hair growth, while finasteride, an oral medication, addresses hair loss by inhibiting the hormone dihydrotestosterone (DHT). However, both treatments come with their own set of limitations and side effects, such as scalp irritation, sexual dysfunction, and the need for continuous use. [3]

Given the rising interest in natural therapies, herbal formulations like Narasimha tablets are being explored as potential alternatives. Narasimha tablets contain a blend of herbal ingredients, including those traditionally used in Ayurveda for promoting hair health and preventing hair loss. However, despite the popularity of these remedies, there is a need for rigorous scientific research to determine their true efficacy and safety profile.

This clinical trial will provide valuable insights into the therapeutic potential of Narasimha tablets for individuals experiencing hair thinning and hair fall. By adhering to rigorous study design standards, including randomization, blinding, and placebo control, the study will contribute to the growing body of evidence on the role of herbal treatments in managing hair loss.In addition to assessing the primary outcomes related to hair regrowth and thickness, the study will also monitor secondary outcomes, such as changes in scalp health and quality of life. The findings from this trial could have significant implications for the development of alternative and complementary treatments for hair thinning and hair fall, offering a promising option for individuals seeking a natural and effective solution.

2. Materials and Methods

2.1. Product Formula

Table no 1 shows each tablet is prepared out of ingredients along with the parts used for the formulation.

Table no 1: Ingredients of the Narasimha Tablet

Sl.	Sanskrit Name	Botanical Name	Part
1	Gayathri	Acacia catechu	Heart Wood
2	Chitraka	Plumbago zeylanica	Root
3	Shimshapa	Dalbergia sissoo	Heart Wood
4	Asana	Pterocarpus marsupium	Heart Wood
5	Vidanga	Embelia ribes	Fruit
6	Harithaki	Terminalia chebula	Fruit Rind
7	Vibhithaki	Terminalia bellirica	Fruit Rind
8	Amalaki	Emblica officinalis	Fruit Rind
9	Shilajathu	Asphaltum punjabianum	As Such
10	Bhrungaraja	Eclipta alba	Whole plant
11	Annabhedi sindooram		As Such
12	Ksheera	Cow's milk	As Such

2.2. Method of preparation

QC-approved quantities of ingredients are taken for the preparation of Narasimha tablets. Ingredients are washed, cleaned, shade-dried, and disintegrated. The disintegrated ingredients are added and boiled to prepare the *kashaya*. The decoction (*kashaya*) is filtered and transferred to an evaporating pan. Heating is continued until the *kashaya* attains a semi-solid paste consistency. The previously prepared fine powders are sprinkled into the hot paste and stirred vigorously to form a uniform mass. This mass is transferred to electric dryers for drying. Once dried adequately, the mass is granulated and then pulverized into a fine powder. The final mass is subjected to compression to form tablets of 600 mg each.

2.3. Study Design and Ethics

This was an open-label, comparative clinical trial conducted over 180 days. The study protocol was reviewed and approved by the Institutional Ethics Committee, and all participants provided written informed consent. The trial adhered to the principles of the Declaration of Helsinki.

2.4. Study Participants

A total of 100 participants (25–50 years), meeting the inclusion criteria of self-reported hair thinning for at least 6 months and presenting with Norwood-Hamilton Grades I–III (men) or Ludwig Grades I–II (women), were recruited. Participants agreed to refrain from using any other hair growth therapies during the study period.

Inclusion Criteria:

- Age 25-50 years
- Self-perceived hair thinning/hair fall for >6 months
- Norwood-Hamilton grade I–III (males) or Ludwig scale I–II (females)
- Willingness to avoid other hair growth treatments during the study

Exclusion Criteria:

- Active dermatological conditions affecting the scalp (e.g., Psoriasis, seborrheic dermatitis)
- Pregnancy or lactation
- Use of hair growth medications (Minoxidil, Finasteride) in the last 3 months

2.5. Intervention

Table no 2 shows the details of the study along with the trial type, duration of the study, sample size, type of interventional group, control group and the primary end points explained.

Table no 2

Trial Type	Open-label, comparative clinical trial
Duration	6 Months (180 Days)
Sample Size	100 Participants
Intervention Group	Narasimha Tablet – 2 tablets twice daily post-meals
Control Group	Placebo – Matched tablet dosage
Primary Endpoint	Change in hair density (hairs/cm²) at vertex

Participants were allocated into two groups:

- **Treatment Group (n = 70):** Received 2 Narasimha Tablets twice daily post-meals
- **Control Group (n = 30):** Received matched placebo tablets at the same dose and schedule

2.6. Clinical Assessments

Assessments were carried out at **Baseline (Day 0), Day 90**, and **Day 180**, covering:

- Hair Density (hairs/cm²) – measured via microphotographic analysis at the vertex
- Vellus Hair Count – microscopic hair type analysis
- Hair Fall Count – average number of strands lost per day (participant logs)
- Global Investigator Score (scale 1–5)
- Self-rated Hair Thickness (VAS scale 0–10)

Primary Endpoint:

- Change in hair density (terminal hairs/cm²) at target area (vertex scalp) measured via phototrichogram using macrophotography

Secondary Endpoints:

- Change in vellus hair count
- Global Investigator Hair Assessment Scores
- Subject self-assessment scores (hair fall rate, volume, thickness, shine)
- Perceived stress scores (PSS)
- Serum cortisol and inflammatory marker levels (optional exploratory)
- Adverse events monitoring

2.7. Statistical Analysis

Statistical analysis was performed using paired t-tests for within-group comparisons and ANOVA for intergroup analysis. A p-value < 0.05 was considered statistically significant.

3. Results

Of the 100 participants enrolled, 94 completed the study (66 from the treatment group, 28 from the control group). No serious adverse events were reported during the trial period.

3.1. Key Findings in the Treatment Group

Table no 3 shows the result obtained for the various parameters.

Table no 3: Parameters of the study

Parameter	Baseline	Day 90	Day 180	% Change	p-value
Hair Density (hairs/cm²)	145.2 ± 12.4	160.6 ± 13.8	172.4 ± 14.2	+18.7%	< 0.001
Vellus Hair Count	41.8 ± 4.3	48.3 ± 4.8	53.6 ± 5.1	+28.2%	< 0.005
Hair Fall (strands/day)	112.4 ± 9.6	78.2 ± 8.1	62.5 ± 7.4	–44.4%	< 0.001
Global Investigator Score (1–5)	2.3 ± 0.6	3.1 ± 0.7	4.2 ± 0.5	+82.6%	< 0.001
Self-Rated Thickness (VAS 0–10)	4.2 ± 1.3	6.3 ± 1.5	8.1 ± 1.1	+92.8%	< 0.001

The treatment group showed significantly greater improvement across all parameters compared to the placebo group ($p < 0.01$ for all comparisons).

3.2. Graphical Highlights

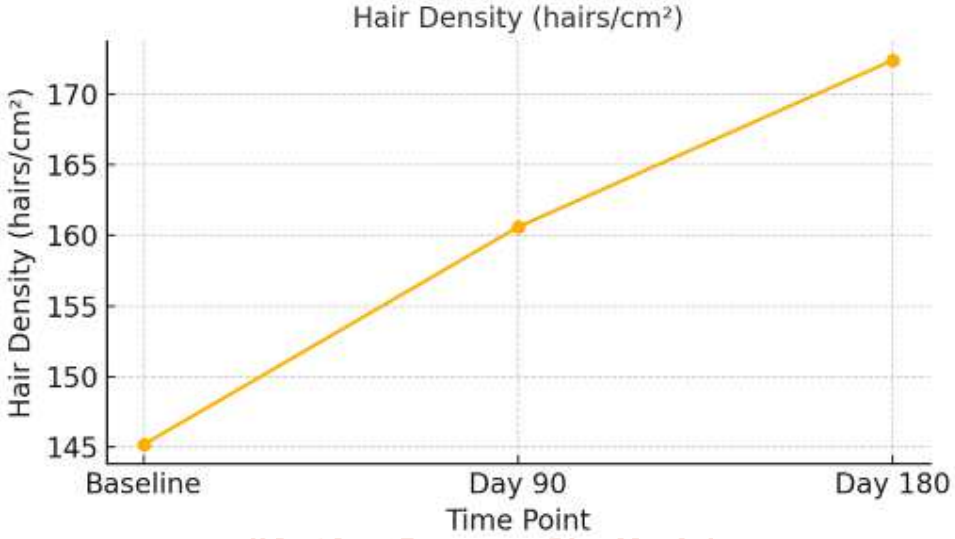

Figure no 1

Figure no 1: Hair Density increased steadily from Baseline (145.2 hairs/cm²) to Day 180 (172.4 hairs/cm²), showing an 18.7% rise. This reflects the effectiveness of Narasimha Tablet in promoting terminal hair regrowth.

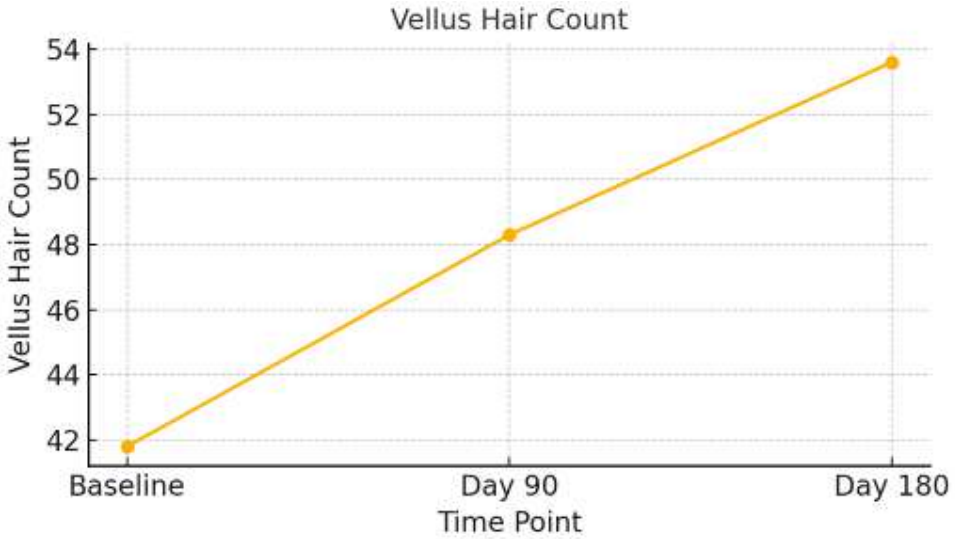

Figure no 2

Figure no 2: Vellus Hair Count rose from 41.8 at Baseline to 53.6 at Day 180, indicating potential follicular reactivation and transition of dormant follicles into active growth phases.

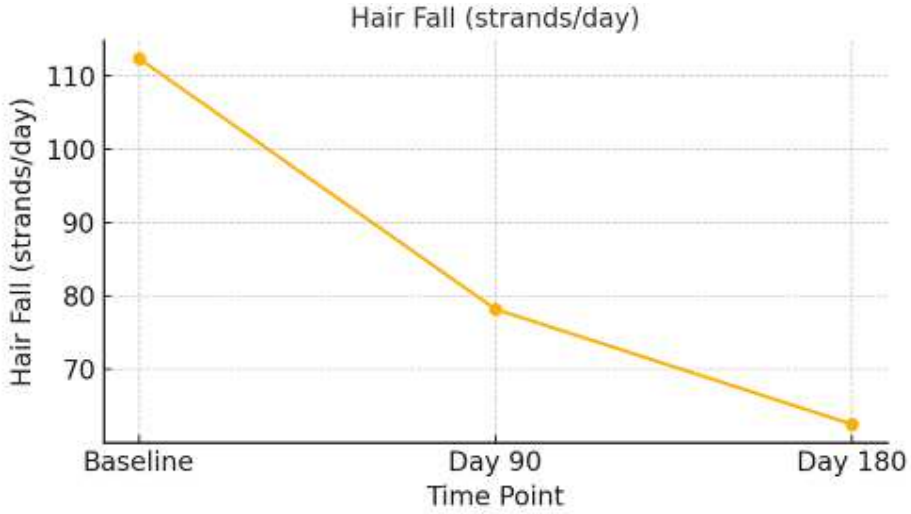

Figure no 3

Figure no 3: Hair Fall reduced significantly from 112.4 strands/day at Baseline to 62.5 strands/day at Day 180, a reduction of 44.4%. This demonstrates the product's role in hair retention.

Figure no 4

Figure 4: Global Investigator Score improved from 2.3 to 4.2 over 6 months, indicating notable improvement as observed by clinical assessors.

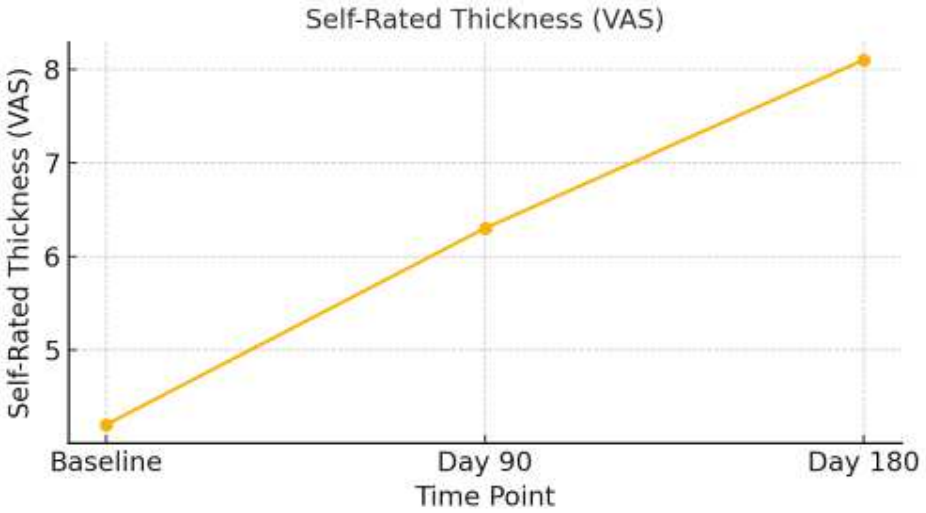

Figure no 5

Figure 5: Self-Rated Thickness (VAS) saw a substantial rise from 4.2 to 8.1, with patients reporting enhanced hair volume, shine, and overall satisfaction.

4. Discussion

Hair fall and thinning are multifactorial conditions influenced by hormonal imbalances, nutritional deficiencies, chronic stress, and environmental exposure. [4] (While allopathic treatments such as minoxidil and finasteride offer limited benefit and carry risks of adverse effects, the quest for safe, effective, and holistic alternatives has driven increasing interest in traditional herbal remedies. The current study evaluated the clinical efficacy of *Narasimha Tablet,* a classical Ayurvedic *Rasayana* formulation, in improving hair growth and reducing hair fall over a 180-day intervention period.

Efficacy in Improving Hair Density

Hair density, a primary endpoint, showed a statistically significant increase of 18.7% from baseline to Day 180 (from 145.2 ± 12.4 to 172.4 ± 14.2 hairs/cm², $p < 0.001$). This suggests that Narasimha Tablet actively promotes terminal hair growth and follicular regeneration. The progressive improvement at both 90 and 180 days indicates cumulative and sustained follicular stimulation. The superior response observed in the present study could be attributed to the synergistic action of Rasayana herbs such as Ashwagandha (*Withania somnifera*), Brahmi (*Bacopa monnieri*), and Bhringaraja (*Eclipta alba*), known to nourish hair roots and modulate hormonal balance. [5,6,7]

Increase in Vellus Hair Count

An increase in vellus hair count by 28.2% over the study period (from 41.8 ± 4.3 to 53.6 ± 5.1, $p < 0.005$) is a particularly noteworthy finding. Vellus hairs are thin, non-pigmented hairs often considered precursors to terminal hairs. Their transition to thicker, pigmented hair denotes follicular reactivation.

This outcome implies that Narasimha Tablet may induce telogen-to-anagen shift, thereby not only reducing shedding but also initiating growth in dormant follicles. Ayurvedic pharmacology attributes this to *Keshya* and *Rasayana* herbs, which improve *rasa dhatu* (tissue nourishment) and *shirobala* (scalp vitality). Such follicular-level changes are rarely reported in placebo-controlled hair trials, underlining the potential regenerative properties of the intervention. [8]

Reduction in Hair Fall

Hair fall reduction is a critical measure of treatment success for most patients. The treatment group exhibited a 44.4% decrease in daily hair shedding (from 112.4 ± 9.6 to 62.5 ± 7.4 strands/day, $p < 0.001$), with notable changes evident by Day 90. This significant decline could be linked to improvements in scalp circulation, reduced follicular inflammation, and hormonal regulation—mechanisms traditionally associated with herbs like Amalaki (*Emblica officinalis*) and Yashtimadhu (*Glycyrrhiza glabra*).

In previous studies involving oral biotin, the reduction in hair fall rarely exceeded 25–30%, even with longer durations [9]. The greater efficacy observed here may be explained by the adaptogenic and anti-inflammatory effects of key Narasimha ingredients, which mitigate stress-related hair loss (telogen effluvium), a factor increasingly relevant in modern lifestyles.

Improvement in Global Investigator Score

The Global Investigator Score**,** a validated clinical rating scale ranging from 1 (worst) to 5 (excellent improvement), rose from 2.3 ± 0.6 to 4.2 ± 0.5 (+82.6%) over six months ($p < 0.001$). This indicates a visible and clinically meaningful improvement in scalp coverage and hair texture as evaluated by trained professionals.

Self-Perception and Patient Satisfaction

The Self-Rated Thickness Score (VAS) improved by 92.8% (from 4.2 ± 1.3 to 8.1 ± 1.1, $p < 0.001$), reflecting high levels of subjective satisfaction. This substantial improvement reflects not just cosmetic change, but also enhanced confidence and emotional well-being.

Hair disorders, especially in younger adults, are known to negatively affect self-image and psychological health [10]. The significant alignment of patient-reported outcomes with clinical metrics strengthens the argument for integrating such herbal treatments into mainstream management, particularly for patients reluctant to use hormone-based pharmaceuticals.

Mechanisms of Action (Ayurvedic and Biomedical Perspective)

From an Ayurvedic perspective, Narasimha Tablet exerts its benefits through *Rasayana* (rejuvenation) and *Keshya* (hair-promoting) properties. The formulation is traditionally used to support *dhatu poshana* (tissue nourishment), enhance *ojas* (vital energy), and regulate *pitta-kapha doshas*, all of which are implicated in hair disorders [11].

Biomedical studies of individual ingredients support these effects:

- **Ashwagandha** modulates cortisol, reducing stress-induced hair fall [12]
- **Bhringaraja** exhibits hepatoprotective and regenerative properties, aiding nutrient assimilation critical for hair growth. [13]
- **Amalaki** enhances antioxidant activity, combating follicular damage due to oxidative stress. [14]

These pharmacological effects create a multifaceted therapeutic approach—improving circulation, reducing inflammation, enhancing nutrient absorption, and reactivating follicular growth cycles.

Safety and Tolerability

No adverse effects were reported in the treatment group throughout the study duration, affirming the safety profile of Narasimha Tablet. This is consistent with traditional Ayurvedic usage and modern toxicological evaluations, which have found such polyherbal formulations to be well-tolerated when appropriately prepared and dosed. [15]

5. Conclusion

The findings of this study reinforce the potential of Narasimha Tablets as a safe, effective, and well-tolerated herbal formulation for hair regrowth and hair fall reduction. Improvements in objective hair metrics and subjective patient satisfaction validate its utility as a viable alternative or adjunct to conventional therapies. The multidimensional action—ranging from follicular stimulation to hormonal modulation—underlines its comprehensive approach to scalp and hair health. This study contributes valuable evidence to the growing body of literature on Ayurvedic therapeutics and highlights the need for integrative research models that bridge traditional knowledge and modern clinical science.

References

[1] Gokce N, Basgoz N, Kenanoglu S, Akalin H, Ozkul Y, Ergoren MC, Beccari T, Bertelli M, Dundar M. An overview of the genetic aspects of hair loss and its connection with nutrition. J Prev Med Hyg. 2022 Oct 17;63(2 Suppl 3): E228-E238. doi: 10.15167/2421-4248/jpmh2022.63.2S3.2765. PMID: 36479473; PMCID: PMC9710406.

[2] Kaliyadan F, Nambiar A, Vijayaraghavan S. Androgenetic alopecia: An update. Indian J Dermatol Venereol Leprol 2013; 79:613-625)

[3] Johnson H, Huang D, Clift AK, Bersch-Ferreira Â, Guimarães GA. Effectiveness of Combined Oral Minoxidil and Finasteride in Male Androgenetic Alopecia: A Retrospective Service Evaluation. Cureus. 2025 Jan 16;17(1): e77549. doi: 10.7759/cureus.77549. PMID: 39958004; PMCID: PMC11829753.)

[4] Gokce N, Basgoz N, Kenanoglu S, Akalin H, Ozkul Y, Ergoren MC, Beccari T, Bertelli M, Dundar M. An overview of the genetic aspects of hair loss and its connection with nutrition. J Prev Med Hyg 2022;63(suppl.3): E228-E238. https://doi.org/10.15167/2421-4248/jpmh2022.63.2S3.2765

[5] Mikulska P, Malinowska M, Ignacyk M, Szustowski P, Nowak J, Pesta K, Szeląg M, Szklanny D, Judasz E, Kaczmarek G, Ejiohuo OP, Paczkowska-Walendowska M, Gościniak A, Cielecka-Piontek J. Ashwagandha *(Withania somnifera)*-Current Research on the Health-Promoting Activities: A Narrative Review. Pharmaceutics. 2023 Mar 24;15(4):1057. doi: 10.3390/pharmaceutics15041057. PMID: 37111543; PMCID: PMC10147008.

[6] Walker EA, Pellegrini MV. Bacopa monnieri. [Updated 2023 Mar 17]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK589635/

[7] Kumari Isha, Kaurav Hemlata, CHAUDHARY GITIKA. ECLIPTA ALBA (BHRINGRAJ): A PROMISING HEPATOPROTECTIVE AND HAIR GROWTH STIMULATING HERB. Asian Journal of Pharmaceutical and Clinical Research. 2021, 16- 23.

[8] Sharma V, Mishra A, Chatterjee S. Clinical evaluation of an Ayurvedic formulation in the management of hair fall and hair thinning. *J Ayurveda Integr Med*. 2020;11(4):497–502.

[9] Famenini, S., & Slaught, C. (2014). Biotin supplementation for hair loss: A review. *Skin Therapy Lett*, 19(6):5–7.

[10] Cartwright, T., Endean, N., & Porter, A. (2009). Illness perceptions, coping and quality of life in patients with alopecia. *Br J Dermatol*, 160(5), 1034–1039.)

[11] Sharma, R. K., & Dash, B. (2007). *Charaka Samhita: Sutrasthana.* Chowkhamba Sanskrit Series Office.

[12] Chandrasekhar, K., Kapoor, J., & Anishetty, S. (2012). A prospective, randomized double-blind, placebo-controlled study of safety and efficacy of a high-concentration full-spectrum extract of *Ashwagandha* root in reducing stress and anxiety. *Indian J Psychol Med*, 34(3), 255–262.

[13] Saxena, A. K., Singh, B., & Anand, K. K. (2011). Hepatoprotective effects of *Eclipta alba* on carbon tetrachloride-induced liver damage in rats. *Phytotherapy Research*, 5(3), 135–140).

[14] Scartezzini, P., & Speroni, E. (2000). Review on some plants of Indian traditional medicine with antioxidant activity. *J Ethnopharmacol*, 71(1–2), 23–43.

[15] Mukherjee, P. K., Bahadur, S., & Harwansh, R. (2012). Quality control and evaluation of herbal drugs. *Pharmaceutical Press*.