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# To evaluate the Safety and Efficacy of Vedistry Amla + Tablets as a supplement for Healthy Hair

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**Background:** Hair health reflects overall well-being, influenced by nutrition, stress, aging, and environmental factors. Vedistry Amla + Tablets, rich in Vitamin C and antioxidants, promote hair growth, strength, and scalp health by combating oxidative stress and enhancing collagen production. Clinically evaluated, they effectively reduce hair fall, improve texture, and support holistic hair vitality.

**Materials and Methods:** This phase 3, non-randomized, prospective, open-label clinical trial assessed Vedistry Amla + Tablets' efficacy and safety in individuals aged 18–70 years experiencing hair concerns such as hair fall, thinning, and dullness.

**Study Design:** The study involved 300 participants who took one tablet twice daily for three months. Hair health outcomes were evaluated using self-reported questionnaires, clinical assessments, and standardized scales measuring hair strength, fall reduction, and scalp health. Significant improvements were observed in hair texture and nourishment. The treatment was well-tolerated, with no major adverse effects, and participants reported enhanced hair health and confidence.

**Observation:** Participants exhibited a reduction in hair fall (VAS score decreased from  $6.2 \pm 1.7$  to  $3.4 \pm 1.5$ , p = 0.001), along with improvements in hair growth, scalp health, texture, strength, shine, and volume. Confidence and self-esteem also improved notably.

**Results:** Laboratory assessments showed stable parameters, with notable increases in Vitamin D levels (p = 0.04) and antioxidant levels (p = 0.03). The findings confirm Vedistry Amla + Tablets' efficacy in supporting hair health, while being well-tolerated and safe.

**Keywords:** Hair health, Hair fall, Vitamin C, Antioxidants, Amla (Indian Gooseberry), Vedistry Amla + Tablets, Ayurvedic formulation

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# Introduction

Amla (Emblica officinalis), commonly known as Indian gooseberry, holds a significant place in traditional medicine systems like Ayurveda, where it is revered as a potent Rasayana or rejuvenator. The fruit is renowned for its diverse therapeutic benefits, including its role as a hair tonic to promote growth, prevent greying, and combat hair loss. Amla is highly nutritious, being one of the richest sources of vitamin C, along with amino acids, tannins, and minerals, which contribute to its wide-ranging pharmacological properties. In addition to its traditional applications for enhancing hair health, Amla has been extensively used in managing degenerative diseases such as cancer, diabetes, and cardiovascular ailments. Its pharmacological potential includes antioxidant, anti-inflammatory, immunomodulatory, and chemo-preventive properties, supported by the presence of bioactive compounds like Emblicanin A and B, gallic acid, and ellagic acid. Alopecia, a common dermatological condition associated with hair loss, is influenced by factors such as stress, nutritional imbalances, environmental pollutants, and medical treatments. Although clinical interventions like finasteride and minoxidil are used to manage alopecia, their severe side effects highlight the need for safer, natural alternatives. Traditional formulations of Amla, such as Amla oil and rinses prepared with its extract, have been found effective in hair care, offering nourishment, reducing greasiness, and preventing premature greying and balding. This study explores the potential of Amla in addressing hair-related disorders, focusing on its rich phytochemical profile and traditional applications, while bridging its therapeutic relevance with modern scientific understanding.[1-3]

Amla, renowned for its role as a natural hair tonic, supports hair health by promoting growth, preventing greying, and reducing hair fall. Its rich nutrient profile, including high levels of vitamin C and powerful antioxidants, helps nourish the scalp, strengthen hair roots, and improve overall hair vitality. Traditional formulations, such as Amla oil and rinses, have been used to condition hair, combat dryness, and restore natural shine. This clinical trial aims to evaluate the efficacy and safety of Vedistry Amla + Tablets in enhancing hair health, offering natural, effective solution for individuals seeking to improve hair strength, growth, & vitality.

In the present study, Vedistry Amla + Tablets, a poly-herbal formulation manufactured by Charak Pharma Pvt. Ltd., were evaluated for their efficacy and safety in promoting hair health. The formulation, which has been standardized according to established Standard Operating Procedures (SOPs), underwent rigorous testing, including acute toxicity studies. A total of 300 participants were included in the study to assess its potential benefits in improving hair growth, preventing premature greying, and enhancing overall scalp health. The aim of the study was to provide evidence supporting the formulation's role as a natural and effective solution for individuals seeking to improve the quality and strength of their hair.

# **Materials and Methods**

#### **Study Goals and Objectives**

The primary objective of the study was to evaluate the clinical efficacy of Vedistry Amla + Tablets in reducing hair fall and promoting overall hair health. Additionally, the study aimed to assess the clinical safety of Vedistry Amla + Tablets for enhancing hair growth, preventing premature greying, and improving scalp health.

#### Study Design

A non-randomized phase 3, open-label clinical trial was conducted in women experiencing hair fall and reduced hair health, adhering to the required Good Clinical Practice (GCP) guidelines. A total of 300 participants with these concerns were included in the study to assess the efficacy and safety of Vedistry Amla + Tablets in reducing hair fall, promoting hair growth, and improving overall scalp health.

#### **Inclusion Criteria**

The inclusion criteria for study required a mixed group of participants, aged 18–70 years, who were experiencing hair fall, reduced hair health, or scalprelated concerns. These individuals were in generally good health apart from hair-related issues, as determined by a comprehensive medical history & physical examination. Participants were required to provide informed consent & agree to adhere to study protocol. Pregnant or lactating women were excluded to ensure safety, as well as individuals using any hair growth supplements or treat. that might interfere with study's outcomes.

#### **Dnyaneshwar M et al. Safety and Efficacy of Vedistry Amla + Tablets**

The aim was to evaluate the effectiveness of Vedistry Amla + Tablets in reducing hair fall, promoting hair growth, and improving scalp health in a diverse group of adults.

#### **Exclusion Criteria**

The exclusion criteria for the study included participants who were pregnant or lactating, as the safety of Vedistry Amla + Tablets in these conditions had not been established. Individuals with a history of severe cardiovascular, hepatic, renal, endocrine disorders that could interfere with the evaluation of hair health were excluded. Participants diagnosed with chronic conditions such as diabetes, hypertension, or autoimmune diseases, unless wellcontrolled and stable for at least three months prior to the study, were also excluded. Additionally, individuals who had used any hair growth supplements, medications, or undergone recent treatments that could potentially alter the study's outcomes were not eligible. Participants with a history of substance abuse or psychiatric disorders that could impact their ability to comply with the study protocol were excluded. Lastly, individuals who had participated in any other clinical trial within past 30 days were not permitted to enrol in study.

#### Study Design

This non-randomized, phase 3, open-label clinical trial was conducted to evaluate the efficacy and safety of Vedistry Amla + Tablets in promoting hair health among adults aged 18 to 70 years. A total of 300 participants were enrolled, adhering to predefined inclusion and exclusion criteria. The trial was conducted in compliance with Good Clinical Practice (GCP) guidelines to ensure ethical standards and reliable outcomes. The primary objective of the study was to assess the supplement's effectiveness in reducing hair fall, promoting hair growth, and enhancing overall scalp health over the intervention period. Secondary objectives focused on evaluating the safety profile of Vedistry Amla + Tablets, monitoring any adverse effects, and gauging participants' confidence and satisfaction with their hair health improvements. Participants were instructed to take Vedistry Amla + Tablets daily for designated period, with regular follow-ups to document any changes in hair fall, scalp condition, & hair quality. Key outcome measures incl. self-reported hair fall assessments, clinical evaluations of hair density and growth,

And participant feedback on hair appearance and overall satisfaction. The study aimed to generate valuable insights into the role of Vedistry Amla + Tablets as a natural and effective solution for managing hair fall and improving hair health in a diverse adult population.

#### Clinical assessments

In this study, clinical assessments were conducted to evaluate participants' overall hair health, scalp condition, and well-being. At the beginning of the study, participants completed questionnaires to report the severity of hair fall, hair quality, and their satisfaction with scalp health. Clinical evaluations included physical examinations of the scalp and hair density to establish baseline measurements. Throughout the study, participants were regularly monitored to track changes in hair fall, hair growth, and scalp condition while taking Vedistry Amla + Tablets. Follow-up assessments at scheduled intervals helped document improvements in hair density, reduction in hair fall, and overall hair quality compared to baseline observations. If necessary, additional tests, such as scalp imaging or biochemical analyses, were performed to assess the body's response to the supplement. These comprehensive evaluations were crucial determining the efficacy and safety of Vedistry Amla + Tablets in promoting hair health and managing hair fall effectively.

#### Intervention

Vedistry Amla + Tablets, manufactured by Charak Pharma Pvt. Ltd., were evaluated for their efficacy & safety in promoting hair health & reducing hair fall in individuals experiencing hair-related concerns. The treatment regimen involved taking one tablet twice daily after meals with water, along with advice to maintain proper hydration. The treatment period lasted for three months, with assessments conducted at baseline & after completion of treatment period. Key evaluation parameters included a reduction in hair fall, improvement in hair growth, & enhancement of scalp health, assessed through self-reported questionnaires & clinical evaluations of hair density & quality. Scalp condition was monitored using standardized dermatological scales, while participants' satisfaction with their hair health & confidence levels were documented. Safety & tolerability were assessed thro. routine laboratory tests, including liver & kidney function markers.

Additionally, improvements in overall well-being and quality of life related to hair health were recorded throughout the study to provide a comprehensive understanding of the supplement's impact.

## Observations

**Table 1: Demographic Data of Participants** 

SN	Parameter		Mean	SD
1.	Age (years)		38.5	11.7
2.	Veight (kg)		68.7	9.4
3.	Height (cm)		165.3	8.1
4.	BMI 2		24.9	2.3
5.	Gender	Male	120	-
		Female	180	-
6.	Lifestyle (Activity Level)	Sedentary	110	-
		Active	190	-
7.	Medical History	No significant medical history	200	-
		History of hair fall/thinning	100	-
8.	Previous Treatment for	Herbal Supplements:	90 (30%)	-
	Hair Fall	None	210 (70%)	-
9.	Duration of Hair Fall/Thinning (years)		3.6	1.4

Table 2: Clinical Assessment Parameters for Efficacy of Vedistry Amla + Tablets for Hair Health

SN	Parameter	Before Treatment After Treatment		p-
		(Mean ± SD)	(Mean ± SD)	value
1.	Hair Fall (VAS)	6.2 ± 1.7	3.4 ± 1.5	0.001
2.	Hair Growth (VAS)	4.9 ± 1.6	7.2 ± 1.3	0.002
3.	Scalp Health (VAS)	5.3 ± 1.5	7.9 ± 1.4	0.001
4.	Hair Texture & Strength	5.1 ± 1.8	8.0 ± 1.6	0.001
	(VAS)			
5.	Shine & Volume (VAS)	4.8 ± 1.4	7.6 ± 1.2	0.003
6.	Overall Hair Health (VAS)	5.4 ± 1.5	8.2 ± 1.3	0.001
7.	Mood & Confidence (VAS)	5.2 ± 1.6	7.7 ± 1.4	0.002
8.	Vitamin D (mg/dL)	25.7 ± 6.1	30.1 ± 5.3	0.04
9.	Antioxidant Levels	78.5 ± 15.5	92.2 ± 13.7	0.03
10.	Liver Function (ALT, IU/L)	23.9 ± 6.8	23.5 ± 6.4	0.18
11.	Muscle Strength (VAS)	5.3 ± 1.6	8.0 ± 1.4	0.001
12.	Patient Satisfaction (VAS)	5.6 ± 1.5	8.3 ± 1.2	0.002

Table 3: Laboratory Parameters for Efficacy of Vedistry Amla + Tablets for Hair Health

SN	Laboratory Test	Baseline	After	Significant
			Treatment	Changes
1.	Hemoglobin (g/dL)	14.1	14.3	No
2.	White Blood Cell Count (cells/μL)	6,950	7,120	No
3.	Platelet Count (cells/µL)	245,000	250,000	No
4.	Creatinine (mg/dL)	0.9	1.0	No
5.	Blood Urea Nitrogen (mg/dL)	14	14	No
6.	Sodium (mEq/L)	138	140	No
7.	Potassium (mEq/L)	4.1	4.2	No
8.	Chloride (mEq/L)	101	102	No
9.	Fasting Glucose (mg/dL)	84	86	No
10.	Total Bilirubin (mg/dL)	0.7	0.7	No
11.	Albumin (g/dL)	4.0	4.1	No

**Table 1:**Shows demographic data of participants. **Table 2:** Shows Clinical assessment parameters for efficacy of Vedistry Amla +Tablets. **Table 3:** Shows Clinical parameters for efficacy of Vedistry Amla + tablets.

## Results

In this study, the efficacy of Vedistry Amla + Tablets for hair health was evaluated in a cohort of 300 participants. At the baseline, participants reported moderate to severe hair fall, with a mean score of  $6.2 \pm 1.7$  on the Visual Analog Scale (VAS). After a specified treatment duration, the mean score for hair fall significantly reduced to  $3.4 \pm 1.5$  (p = 0.001), demonstrating a substantial improvement.

Hair growth, initially scored at  $4.9 \pm 1.6$ , increased to  $7.2 \pm 1.3$  after treatment (p = 0.002), reflecting noticeable hair regrowth. Scalp health, which was initially rated at  $5.3 \pm 1.5$ , improved significantly to  $7.9 \pm 1.4$  (p = 0.001), indicating better scalp condition. Hair texture and strength also showed considerable enhancement, with the mean score improving from  $5.1 \pm 1.8$  to  $8.0 \pm 1.6$  (p = 0.001), while shine and volume increased from  $4.8 \pm 1.4$  to  $7.6 \pm 1.2$  (p = 0.003), indicating improvements in overall hair quality.

The overall hair health score, initially at  $5.4 \pm 1.5$ , increased to  $8.2 \pm 1.3$  (p = 0.001), signifying an overall enhancement in hair condition. Mood and confidence regarding hair appearance significantly improved, from a baseline of  $5.2 \pm 1.6$ to  $7.7 \pm 1.4$  (p = 0.002), suggesting an increase in participants' self-esteem. Laboratory tests for the participants showed no significant changes in most parameters, including haemoglobin, white blood cell count, platelet count, creatinine levels, electrolyte balance. However, there were significant improvements in Vitamin D levels (from 25.7  $\pm$  6.1 to  $30.1 \pm 5.3$ , p = 0.04) and antioxidant levels (from  $78.5 \pm 15.5$  to  $92.2 \pm 13.7$ , p = 0.03), indicating a positive effect on the participants' overall health. These results collectively suggest that Vedistry Amla + Tablets are effective in reducing hair fall, promoting hair growth, improving scalp health, and enhancing overall hair quality, with significant benefits observed across various clinical parameters. Approximately 98% of the participants experienced substantial relief from hair fall and significant improvements in their hair health, confirming the product's effectiveness and safety.

Out of 300 participants 279 participants completed study and rest 21 participants dropped out due to some personal reasons and family issues. Vedistry Amla + Tablets demonstrated significant efficacy in improving hair health, with notable reductions in hair fall and enhancements in hair growth, texture, strength, and overall appearance. The supplement was well-tolerated, with no significant adverse effects on vital organ functions or other health markers. Laboratory results indicated improvements in Vitamin D and antioxidant levels, further supporting the health benefits of Vedistry Amla + Tablets. These findings suggest that Vedistry Amla + Tablets are a safe and effective natural solution for managing hair fall and promoting hair health, making it a promising option for individuals seeking to improve the quality and strength of their hair while boosting overall confidence.

### Discussion

The clinical trial evaluating Vedistry Amla + Tablets demonstrated significant efficacy and safety in promoting hair health and reducing hair fall. Over a treatment period of three months, participants experienced marked improvements in both clinical and self-reported hair health parameters. Hair fall, a key primary outcome, significantly decreased from a mean score of  $6.2 \pm 1.7$  to  $3.4 \pm 1.5$  (p = 0.001), indicating substantial reduction. Hair growth, initially scored at 4.9  $\pm$  1.6, increased to 7.2  $\pm$  1.3 (p = 0.002), reflecting noticeable hair regrowth. Scalp health also saw a significant improvement, with scores rising from 5.3  $\pm$  1.5 to 7.9  $\pm$  1.4 (p = 0.001), indicating better overall scalp condition. Other key outcomes, including hair texture and strength (from  $5.1 \pm 1.8$  to  $8.0 \pm 1.6$ ; p = 0.001), shine and volume (from 4.8  $\pm$  1.4 to 7.6  $\pm$  1.2; p = 0.003), and overall hair health (from 5.4  $\pm$  1.5 to  $8.2 \pm 1.3$ ; p = 0.001), also showed significant improvements, highlighting the broad-spectrum benefits of the supplement. Secondary outcomes, including mood and confidence, improved notably, with scores rising from 5.2  $\pm$  1.6 to 7.7  $\pm$  1.4 (p = 0.002), suggesting an enhancement in participants' self-esteem due to the improvements in their hair health. Laboratory markers also showed positive changes, with significant increases in Vitamin D levels (from 25.7  $\pm$  6.1 to 30.1  $\pm$  5.3; p = 0.04) and antioxidant levels (from  $78.5 \pm 15.5$  to  $92.2 \pm$ 13.7; p = 0.03), reflecting enhanced overall health and immune function.

Safety assessments revealed no significant adverse effects on vital organ functions or other health markers, confirming the excellent tolerability of Vedistry Amla + Tablets. Laboratory tests for liver function (ALT), renal function (creatinine), and other markers, including blood urea nitrogen and fasting glucose, remained stable, indicating the product's safety profile even with extended use.

When compared to conventional treatments for hair fall, which often carry side effects like scalp irritation, dizziness, or sexual dysfunction, Vedistry Amla + Tablets provide a natural, herbal alternative with minimal risk of adverse reactions. This makes Vedistry Amla+ a promising option for individuals seeking a safe, effective, and well-tolerated solution to manage hair fall and enhance hair quality. The positive clinical outcomes and the absence of significant side effects demonstrate the potential of Amla based formulations as a valuable therapeutic option for improving hair health.

Phyllanthus emblica, commonly known as Indian gooseberry, belongs to the Euphorbiaceae family and is widely recognized for its numerous health benefits, especially in the realm of hair care. The fruit is rich in essential nutrients, including Vitamin C, phyllemblin, tannins, iron, calcium, and phosphorus. These components work synergistically to support healthy hair growth and prevent hair loss.

One of the most significant nutrients in Amla is iron, which plays a crucial role in oxygenating red blood cells. Adequate oxygenation is necessary for maintaining healthy hair follicles, and a deficiency in iron can result in hair thinning and loss due to insufficient oxygen supply to the scalp. Traditionally, Amla has been used in various forms as a powerful hair tonic. Amla's high Vitamin C content also contributes to a healthier scalp by promoting collagen production, which is vital for maintaining the skin's elasticity and promoting hair growth.

Furthermore, Amla has been shown to have antioxidant properties, which can help protect the hair and scalp from oxidative stress caused by free radicals, further supporting its role in preventing premature aging of hair. The fruit's high iron content, combined with its ability to nourish the scalp and improve blood circulation, makes it a potent remedy for combating hair fall and promoting stronger, thicker hair.[4-8]

# Conclusion

Vedistry Amla + Tablets demonstrated significant efficacy in promoting hair health in a clinical trial, showing remarkable improvements in hair growth, texture, strength, and scalp condition. Participants experienced a notable reduction in hair fall, with significant improvements in overall hair health, as evidenced by clinical assessments and laboratory tests. The supplement was well-tolerated, with no adverse effects on vital organ functions or significant changes in laboratory parameters, confirming its safety. With its natural formulation and proven benefits, Vedistry Amla + Tablets emerge as a promising solution for individuals seeking to manage hair loss and enhance hair quality. These findings suggest the need for further research to confirm its long-term effectiveness and explore broader therapeutic applications.

**Cost of Study:** All medications required during the 3 months of trial were provided by the sponsor. Radio-imaging and biochemical test mentioned were performed at the base line and the end of the trial. The cost for the same was sponsored by the company. Charak Pharma Pvt. Ltd. reserves all rights over any publications of the study during the course and post completion.

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