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To evaluate safety and efficacy of Keshohills hair oil in subjects with mild to moderate hair fall and dandruff

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ABSTRACT

Introduction - Hair fall is one of the minor diseases which is affecting approximately 1.7% of the world population and challenging task for physicians. Treating Hair issues with ayurvedic medicated oils have gained importance due to the safety and efficacy of their use. Keshohills hair oil is Ayurvedic proprietary medicine formulated as oil with herbs aimed at reducing hair fall and scalp dandruff. **Objective** - The aim of this clinical study was to evaluate the effectiveness of Keshohills hair oil in the management of hair fall and dandruff of the scalp in adults. **Materials and Methods** - 50 healthy respondents were enrolled and completed the period of study positively. The 60 Second Hair Comb Test, Adherent Scalp Flaking Score, Objective Hair Assessment Questionnaire, were used in the study. **Conclusion** - Keshohills hair oil was effective in reducing hair loss, treating Seborrheic dermatitis.

Key words: Keshohills hair oil, Hair fall, dandruff, Hair Comb Test, Adherent Scalp Flaking Score.

INTRODUCTION

Long, vibrant hair in good condition is very beneficial for enhancing personality. In this highly civilized period, the human race is blessed with numerous benefits and sophistication, but they are also left with sedentary lifestyles, hectic schedules, and poor eating practices. One of the many health problems brought on by these habits that disrupt the body's homeostasis is the autumn. The issue of hair loss in society is constantly getting worse, which has a detrimental effect on people's quality of life. Long-term hair loss may have an impact on mental health.

Due to the importance of hair to one's appearance, difficulties including hair loss, dandruff, and greying are

now common, and the hunt for a remedy has boosted the usage of herbal medications that can treat these conditions.

OBJECTIVE

To evaluate the effectiveness of Keshohills hair oil in the management of hair fall and seborrheic dermatitis of the scalp in adults.

MATERIALS AND METHODS

Trial Drug - Each 100 ml Keshohills hair oil contents

SN	Name	Botanical name	Quantity
1.	Henna leaf	<i>Lawsonia inermis</i>	4 Gm
2.	Brahmi leaf	<i>Bacopa monnieri</i>	4 Gm
3.	Aloevera leaf	<i>Aloe barbadensis</i>	4 Gm
4.	Betel leaf	<i>Piper betle</i>	4 Gm
5.	Methi seed	<i>Trigonella foenum graecum</i>	1.25 Gm
6.	Kalonji seed	<i>Nigella sativa</i>	1.25 Gm
7.	Bhrungraj	<i>Eclipta alba</i>	1.25 Gm

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8.	Amla powder	<i>Embilica officinalis</i>	1.25 Gm
9.	Jaswant flower	<i>Hibiscus rosasinensis</i>	2 Gm
10.	Sarso oil	<i>Brassica juncea</i>	0.63 MI
11.	Kapoor oil	<i>Cinnamomum camphora</i>	1 MI
12.	Coconut oil	<i>Cocos nucifera</i>	100 MI
13.	Fragrance (almond)		(QS)

Inclusion criteria

1. Age - 18 to 45 years
2. Gender - Both
3. Symptoms or disease criteria - mild to moderate dandruff and hair fall
4. Subjects who are able to give written informed consent and ready to comply with the protocol.

Exclusion criteria

1. Pre-existing hair or scalp disease other than hair fall.
2. Concomitant medications or treatments affecting the hair (minoxidil, chemotherapy etc.), Use of styling tools, hair dyes, hair perming etc.
3. Allergy/intolerance to the investigational product
4. Subjects who are balding or bald.
5. Subject with other dermatological disorders of the scalp that might interfere with the study evaluation.
6. Subjects who have previously undergone hair transplantation procedures.
7. History of systemic or cutaneous malignancy or evidence of immunocompromised state.
8. Subjects with history of skin allergy.
9. Subjects on systemic steroids for more than 14 days within 2 months prior to enrolment.
10. Female subjects who are reported pregnant/planning a pregnancy or lactating.

50 healthy respondents were enrolled and completed the period of study positively. Out of which 5 cases were drop out cases. Total 45 respondents completed the study. The 60 Second Hair Comb Test, Adherent Scalp Flaking Score.

Baseline Assessments: Subjects will be assessed for the indications of hair fall, dandruff of the scalp.

Improvement Metric

Subjects will be assessed for the indications of hair fall, dandruff of the scalp, every 15 days to analyze improvement metric.

1. At screening on day 1 (Visit 1), Volunteers after giving written informed consent, given screening numbers and subjected to screening procedures. Eligible volunteers were enrolled in the study and Medical History along with physical examination and demography was collected.
2. All selected 50 subjects were provided with Investigational Hair Oil.
3. The subjects were instructed to use the oil (quantity depending upon the length of hair) daily after hair wash. Subjects were asked to massage the scalp and comb hair, shake the bottle well to evenly distribute the medicinal content.

They were instructed to do the following:

1. Take 5ml of oil on palm and rub together, apply the oil onto scalp and from root to tip of hair. Massage well for 3-5 minutes and leave on. Use a mild shampoo once in every 3 days to wash hair.
2. On other days wash hair with water alone if required.
3. Subject's feedback on product smell, smell of hair after applying the product, existence of smell on the hair will be done using subject feedback sheet during final visit by subject.
4. The subjects will be asked to inform the investigator in case they take any medication for any condition during the study term/period.

Clinical end points assessment

Primary and Secondary End Points

- Hair fall** - Hair fall assessment by manual count by the 60 Second Hair Comb Test.

The objective improvement evaluation included; i.e. 1. Mean number of hair lost during one minute combing test > 150 hairs lost = Poor (Score-3); 100 - 150 hairs lost = Fair (Score-2) and 50 – 100 hairs lost = Good (Score-1).

- Dandruff** - assessment was done by Adherent Scalp Flaking Score (ASFS), itching on Scalp.

Adherent Scalp Flaking Score (ASFS)

The subject's scalp was divided into 8 zones which were assessed for dandruff flakes (Tab. 3) on a score of 0–10 i.e.

Grade Standard Established, 0- No scales, 2- Thin scales, 4- Diffused thin scales, 6- Thick, heaped-up scales, but not forming plaques, 8- Diffused, thick heaped-up scales, but not forming plaques, 10- Very thick heaped-up scales forming plaques

Itching on Scalp-

0- No itching, 1- mild itching, 2- moderate itching, 3- severe itching

- Hair texture** - by roughness of hair 0- no roughness, 1- mild, 2- moderate, 3- very rough

The secondary end point was adverse effects reported by the patients/subjects.

RESULTS AND DISCUSSION

Table 1: Age wise Distribution

Age Group	Frequency	Percentage
< 20 Years	6	13.33%
21-25 Years	11	24.44%
26-30 Years	8	17.78%
31-35 Years	5	11.11%
36-40 Years	9	20.00%

41-45 Years	6	13.33%
Total	45	100.00%

Table 2: Gender wise distribution

Gender	Frequency	Percentage
Male	19	42.22%
Female	26	57.78%
Total	45	100.00%

Table 3: Occupation wise distribution

Occupation	Frequency	Percentage
Housewife	5	11.11%
Service	24	53.33%
Student	16	35.56%
Total	45	100.00%

Table 4: Hair fall, ASFS, Itching on scalp and Hair texture improvement in participants after use of the test

Parameters	Mean		SD		Wilcoxon W	P-Value	% Effect	Result
	BT	AT	BT	AT				
Hair Fall	2.67	1.00	0.48	0.00	-6.092 ^b	0.0000112	62.50	Sig
ASFS	5.51	0.18	1.71	0.58	-5.971 ^b	0.0000235	96.77	Sig
Itching on Scalp	2.31	0.00	0.47	0.00	-6.111 ^b	0.0000099	100.00	Sig
Hair Texture	2.16	0.00	0.37	0.00	-6.323 ^b	0.0000026	100.00	Sig

Since observations are on ordinal scale (gradations), we have used Wilcoxon Signed Rank Test to test efficacy. From above table, we can observe that, P-

Value for all parameters is less than 0.05. Hence, we can conclude that, effect observed in all parameters is significant.

Fig 1: Efficacy Post Treatment

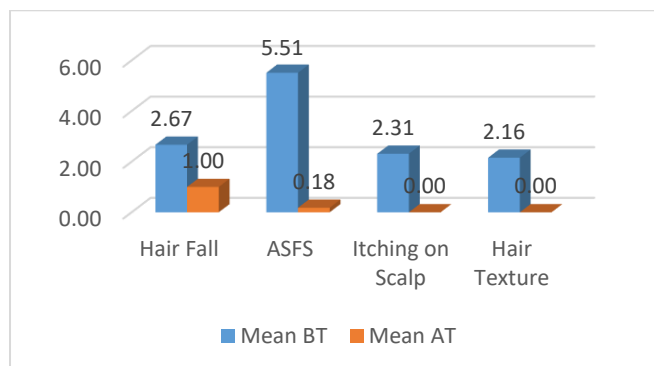


Table 5: Hair fall reduction in participants after use of the test oil by combing assay

Hair Fall	Mean	SD	% Change
Day 0	2.67	0.48	-
Day 15	2.36	0.48	11.67
Day 30	1.78	0.42	33.33
Day 45	1.24	0.43	53.33
Day 60	1.00	0.00	62.50

Fig 2: Follow Up Wise Improvement in Hair Fall

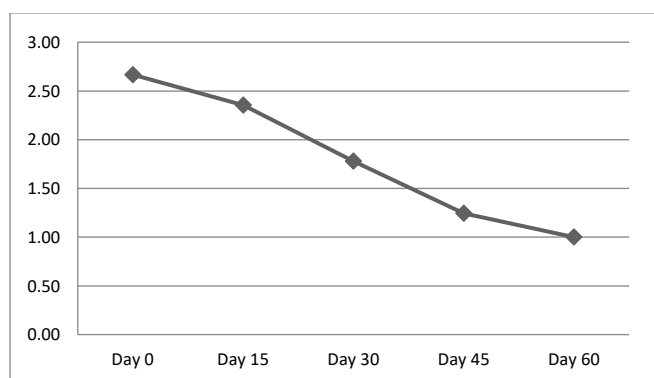


Table 6: ASFS in participants after use of the test oil

ASFS	Mean	SD	% Change
Day 0	5.51	1.71	-
Day 15	4.40	1.68	20.16

Day 30	2.89	1.51	47.58
Day 45	1.16	1.45	79.03
Day 60	0.18	0.58	96.77

Fig 3: Follow Up Wise Improvement in ASFS

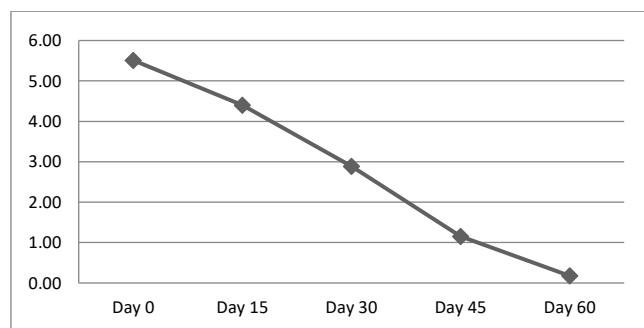


Table 7: Itching on scalp in participants after use of the test oil

Itching on Scalp	Mean	SD	% Change
Day 0	2.31	0.47	-
Day 15	2.09	0.67	9.62
Day 30	1.27	0.50	45.19
Day 45	0.93	0.25	59.62
Day 60	0.00	0.00	100.00

Fig 4: Follow Up Wise Improvement in Itching on Scalp

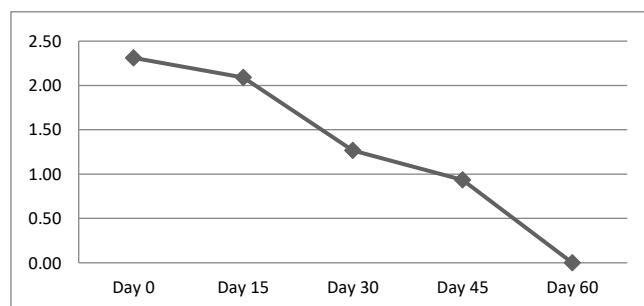
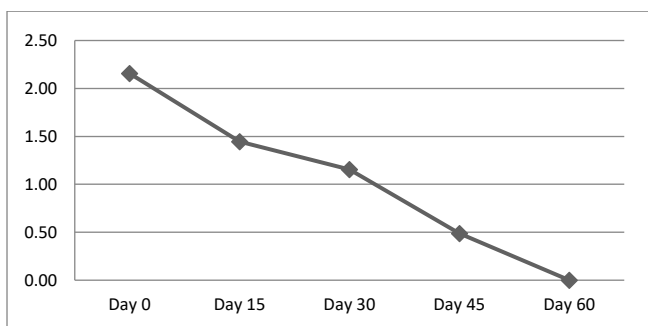


Table 8: Hair texture in participants after use of the test oil

Hair Texture	Mean	SD	% Change
Day 0	2.16	0.37	-
Day 15	1.44	0.50	32.99

Day 30	1.16	0.37	46.39
Day 45	0.49	0.51	77.32
Day 60	0.00	0.00	100.00

Fig 5: Follow Up Wise Improvement in Hair Texture



1. Henna leaf - *Lawsonia inermis*

Therapeutic effect of Henna on androgenic alopecia is possibly achieved by reducing androgen content in local skin tissue.^[1] *Lawsonia inermis* is used as a hair coloring agent in traditional practice. The dyeing substance identified is Lawson and chemically it is anthraquinone or naphthaquinone dye. Henna is also effective against dandruff.^[2]

2. Brahmi leaf - *Bacopa monnieri*

Bramhi work on the hypothalamus-pituitary, adrenal axis and normalize the secretion of neurotransmitters such as dopamine, serotonin, and acetylcholine and can improve mental health which prevents greying of hair.^[3] Hair growth cycle is divided into three phases: Anagen phase (growth), Catagen phase (transition) and telogen phase (rest). Brahmi promotes hair growth by increase in follicular size and a lengthening of the anagen phase.^[4]

3. Aloe vera leaf - *Aloe barbadensis*

Aloe vera is useful in hair loss treatment. The enzyme content of Aloe vera prevents hair loss by protecting scalp against any diseases. It also promotes new hair growth. Seborrheic dermatitis and Dandruff are both caused by an overgrowth of skin yeast. The active ingredient of Aloe vera stimulates two types of cells-Macrophages which engulf foreign microbes and collagen-producing fibroblast cells which help to rebuild and renew the scalp's skin surface. Aloe vera

acts a sun protectant for hair and prevents their damage.^[5]

4. Betel leaf - *Piper betle*

Betel leaves are full of anti-oxidants. Antioxidants are helpful in increasing the blood circulation and thus help in hair growth as well as in the treatment of diseases. Alopecia is a dermatological disorder with psychosocial implications on patients with hair loss. The antioxidant property of this plant can be utilized in hair fall conditions or many diseases.^[6]

5. Methi seed powder - *Trigonella foenum graecum*

Methi seeds are extremely effective against hair fall, dandruff and help to reverse baldness and hair thinning. Fenugreek seeds or Methi contains proteins and nicotinic acid which are a great source for hair growth. It contains large amounts of lecithin which makes our hair healthy and strong, and hydrates the hair. This natural tonic helps in moisturizing the hair and bringing back the lustre and bounce.^[7]

6. Kalonji seed powder - *Nigella sativa*

Nigella sativa seeds have antimicrobial, antioxidant, anti-ageing, hair growth promoter and sun protection activity. This makes it a novel ingredient for this preparation.^[8]

7. Bhringraj powder - *Eclipta alba*

Bhringaraj is indicated for falling of hairs, greying of hairs, alopecia, dandruff and all hairs related disorders in all texts of Ayurveda. Hair growth instigation time and time taken for total hair growth are considerably reduced by its use. Different Phyto constituents present in *Eclipta abla* are responsible for its hair growth promoting activity. β -sitosterol has been tested and established as a potent 5 α - reductase inhibitor. It is present in *E. alba* in appreciable quantity. 5 α - reductase inhibition contributes in treatment of androgenic alopecia and therefore provides a lead for the use of *E. alba* for the aforementioned purposes.^[9]

8. Amla powder - *Emblica officinalis*

Promote hair growth by inhibiting 5 α -reductase activity, Amla is rich in Vitamin C, Vitamin E, and antioxidants, all of which might contribute to cellular

regeneration and promote healthy circulation to the blood vessels in the scalp. These properties may help to facilitate hair and skin growth and boost the overall health of the scalp.^[10]

9. Jaswant flower - *Hibiscus rosasinensis*

Hibiscus Flower: Hibiscus promotes hair growth as it is rich in amino acids, a prime building block of keratin. Keratin is the protein that nourishes, strengthens, and binds the hair roots. Hibiscus is known to improve the build-up of keratin and boost the formation of new hair follicles, thereby stimulating hair growth.^[11]

10. Sarso oil - *Brassica juncea*

Nourishes hair, is a natural conditioner, promotes hair growth and has anti-fungal properties.^[12]

11. Kapoor oil - *Cinnamomum camphora*

Camphor is used to treat head lice and burning sensation. It soothes scalp irritation, prevents dryness and keeps infections away.^[13]

12. Coconut oil - *Cocos nucifera*

The lauric acid in coconut oil has nourishing properties that are especially prone to soak into the strands of your hair. Coconut oil absorbs into your hair quickly, providing moisture to tame frizz and heal breakage.^[14]

CONCLUSION

Keshohills hair oil was safe and effective in reducing hair loss and treating dandruff.

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