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Research Article

A CLINICAL STUDY TO EVALUATE THE EFFICACY OF *KHASA BEEJA TAILA* (SEED OIL OF *PAPAVER SOMNIFERUM* LINN.) IN *DARUNAKA VYADHI*

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ABSTRACT

Darunaka Vyadhi, described under *Kshudra Rogas* and *Kapalagata Rogas* in Ayurvedic texts, is closely related to dandruff - a common scalp disorder. It is characterized by scalp flaking, itching, and dryness without visible inflammation. Classical references suggest the use of *Khasa Beeja Taila* (seed oil of *Papaver somniferum Linn.*) for managing *Darunaka Vyadhi*. **Aim:** To evaluate the efficacy and safety of *Khasa Beeja Taila* (seed oil of *Papaver somniferum Linn.*) as an external application in the management of *Darunaka Vyadhi* (dandruff). **Objectives: Primary Objective:** To assess the anti-dandruff efficacy of *Khasa Beeja Taila* based on reduction in Adherent Scalp Flaking Score (ASFS) and 5D Pruritis Scale. **Secondary Objective:** To evaluate the safety and tolerability of *Khasa Beeja Taila* through clinical observations and hematological parameters (CBP, ESR). **Methods:** An open-label, single-arm pilot clinical study was conducted on 30 subjects diagnosed with *Darunaka Vyadhi*. The intervention involved external application of *Khasa Beeja Taila* twice weekly for four weeks. Efficacy was assessed using the Adherent Scalp Flaking Score (ASFS), 5D Pruritis Scale, and grading scales for *Kandu*, *Twak Sphutana*, *Keshabhoomi Rookshata*, and *Keshachyuti*. Safety assessments included Complete Blood Picture (CBP) and Erythrocyte Sedimentation Rate (ESR) evaluations. **Results:** Statistically significant improvements were noted across all parameters. ASFS and 5D Pruritis Scale showed highly significant reductions ($p<0.0001$) from baseline to the 4th week. Symptoms like *Kandu*, *Twak Sphutana*, *Keshabhoomi Rookshata*, and *Keshachyuti* significantly reduced over the treatment period. No adverse effects or significant changes in CBP and ESR were recorded, confirming the safety of the formulation. **Conclusion:** *Khasa Beeja Taila* demonstrated significant clinical efficacy and safety in managing *Darunaka Vyadhi*. The results indicate its potential as a natural remedy for dandruff and related symptoms, warranting further large-scale studies.

INTRODUCTION

Darunaka Vyadhi is classified under *Kshudra Rogas* and *Kapalagata Rogas* in classical Ayurvedic literature. It is characterized by symptoms like *Kandu* (itching), *Twak Sphutana* (cracking of the scalp skin), *Keshabhoomi Rookshata* (dryness of scalp), *Keshachyuti* (hair fall), and *Pidaka* (small eruptions).[1]

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The predominant involvement of *Vata* and *Kapha Doshas* in its pathogenesis is well documented by *Acharya Sushruta*, *Vagbhata*, and *Sharangadhara*. The features described in Ayurvedic texts correlate closely with the clinical manifestation of dandruff or seborrheic dermatitis of the scalp in modern dermatology.[2]

Dandruff is one of the most prevalent scalp disorders globally, affecting approximately 50% of the pre-pubertal population across genders and ethnicities. It is characterized by flaking of the scalp, itchiness, dryness, and the presence of scales without visible signs of inflammation.[3] Although it is not life-threatening, dandruff significantly impacts the quality of life due to social embarrassment, discomfort, and

chronicity. The exact etiology of dandruff is multifactorial, involving overgrowth of *Malassezia* species, sebaceous gland secretions, individual susceptibility, and environmental factors such as humidity and temperature variations.[4]

Modern medicine offers various topical agents like antifungal shampoos, keratolytic agents, and steroids for managing dandruff. However, these treatments often provide temporary relief and are associated with adverse effects upon prolonged usage, including scalp irritation, dryness, and chemical sensitivity.[5] Additionally, recurrence is a common challenge. As a result, there is a growing interest in exploring safe and effective alternatives through traditional systems like Ayurveda, which provide holistic approaches targeting the root cause of the disorder.[6]

In Ayurveda, the use of *Khasa Beeja Taila* or *Ahiphena Beeja Taila* (seed oil of *Papaver somniferum Linn.*) is traditionally mentioned for external application in *Darunaka Vyadhi*. *Acharya Sharangadhara* highlights the application of *Khasa Beeja Kalka* (paste) with *Godugdha* (cow milk) in scalp disorders. However, oil prepared from *Khasa Beeja* offers a more practical and user-friendly form for application. The pharmacological properties of *Khasa Beeja Taila*, including its *Madhura Rasa*, *Guru* and *Snigdha Guna*, *Madhura Vipaka*, and *Vata-Kapha Hara* actions, make it suitable for managing dryness, scaling, and itching associated with dandruff.[7]

The seed oil of *Papaver somniferum* is rich in linoleic acid, oleic acid, palmitic acid, stearic acid, and tocopherols, contributing to its moisturizing, anti-inflammatory, and skin barrier-repairing properties. These attributes suggest its potential utility in improving scalp health, reducing flaking, and controlling microbial growth. The oil's unctuous nature helps alleviate dryness (*Rookshata*), while its pharmacodynamics can help mitigate excessive *Kapha* accumulation manifesting as flakes and scales on the scalp.[8]

Considering the limited availability of standard and effective anti-dandruff treatments in modern medicine and the rich Ayurvedic heritage suggesting *Khasa Beeja Taila*, this clinical study was designed to evaluate its efficacy and safety in patients suffering from *Darunaka Vyadhi*.[9] The present investigation aims to provide clinical evidence supporting the classical claim and offers a safe, natural alternative for managing dandruff.[10]

AIM AND OBJECTIVES

Aim

To evaluate the efficacy and safety of *Khasa Beeja Taila* (seed oil of *Papaver somniferum Linn.*) as an external application in the management of *Darunaka Vyadhi* (dandruff).

Objectives

1. **Primary Objective**

   To assess the anti-dandruff efficacy of *Khasa Beeja Taila* based on reduction in Adherent Scalp Flaking Score (ASFS) and 5D Pruritis Scale.

2. **Secondary Objective**

   To evaluate the safety and tolerability of *Khasa Beeja Taila* through clinical observations and hematological parameters (CBP, ESR).

MATERIALS AND METHODS

Study Design

An open-label, single-arm interventional clinical study was conducted to evaluate the efficacy and safety of *Khasa Beeja Taila* (seed oil of *Papaver somniferum Linn.*) in the management of *Darunaka Vyadhi* (dandruff).

Study Setting

The study was conducted at Government Ayurvedic Teaching Hospital, Warangal, attached to Anantha Laxmi Government Ayurvedic College, Warangal, Telangana.

Study Drug

- Name: *Khasa Beeja Taila*
- Botanical Source: *Papaver somniferum Linn.*
- Part Used: Seeds (*Beeja*)
- Preparation: The oil was prepared through cold-pressed extraction without using heat to retain natural phytoconstituents. The seeds were authenticated by the Department of Botany, Kakatiya University, Warangal.

Sample Size

A total of 30 subjects diagnosed with *Darunaka Vyadhi* were enrolled based on predefined inclusion and exclusion criteria.

Inclusion Criteria

- Subjects aged 18–55 years of either sex.
- Clinically diagnosed with *Darunaka Vyadhi* (dandruff).
- Subjects willing to give informed consent and comply with the study protocol.
- Subjects with moderate to severe dandruff confirmed through ASFS and clinical examination.

Exclusion Criteria

- Subjects with scalp psoriasis, eczema, or other dermatological conditions.
- Pregnant, lactating women, or menopausal females.
- Immunocompromised individuals or those with uncontrolled diabetes.
- Subjects using corticosteroids, antifungal agents, or hair treatments within the last 3 months.
- Known hypersensitivity to topical oils or cosmetics.

Dosage and Mode of Administration: Subjects were instructed to apply *Khasa Beeja Taila* externally over the scalp in a quantity sufficient to cover the affected area, twice weekly, for 4 weeks.[11]

Assessment Criteria

Primary Efficacy Parameters

- Adherent Scalp Flaking Score (ASFS)
- 5D Pruritis Scale

Secondary Efficacy Parameters

- Assessment of *Kandu* (itching), *Twak Sphutana* (scalp skin cracking), *Keshabhoomi Rookshata* (dryness), and *Keshachyuti* (hair fall).

Safety Assessments

- Complete Blood Picture (CBP)
- Erythrocyte Sedimentation Rate (ESR)
- Monitoring of adverse events throughout the study.

Visit Schedule

- **(Day 0):** Consent, screening, CBP, ESR, ASFS, 5D Pruritis Scale, and other grading assessments.
- **Follow-ups:** Weekly assessments on day 7, day 14, and day 28 to monitor efficacy and safety.

Statistical Analysis

Data were analyzed using GraphPad Prism software. Paired t-test was applied to compare baseline and post-treatment values. A p-value <0.05 was considered statistically significant.

Ethical Approval

The study protocol was reviewed and approved by the Institutional Ethics Committee (IEC) of Anantha Laxmi Government Ayurvedic College, Warangal. The trial was registered under Clinical Trial Registry of India (CTRI/2023/05/052349).

Conceptual Study

Darunaka Vyadhi is one of the scalp disorders extensively described in Ayurvedic classics under *Kshudra Roga* and *Kapala Gata Roga*. The term *Darunaka* is derived from the root *'Daruna'*, which denotes roughness, hardness, or cracking. The condition is characterized by dryness of the scalp, scaling or flaking, itching, and hair fall, primarily due to the vitiation of *Vata* and *Kapha Doshas*. In modern medicine, *Darunaka* is commonly correlated with dandruff and, in chronic cases, seborrheic dermatitis of the scalp, both of which are prevalent conditions across all age groups.[12]

Classical References

Acharya Sushruta, *Bhavamishra*, and *Madhava* have described *Darunaka* under *Kshudra Roga*, presenting with symptoms such as *Kandu* (itching), *Rookshata* (dryness), *Twak Sphutana* (cracking of the skin), and *Keshachyuti* (hair fall). In contrast, *Acharya Vagbhata* and *Sharangadhara* categorized *Darunaka* under *Kapala Gata Rogas*, i.e., diseases localized to the scalp region. All these descriptions signify the local manifestation of the vitiated *Vata* and *Kapha Doshas* in the *Keshabhoomi* (scalp).[13]

***Nidana* (Etiology)**

The etiological factors responsible for *Darunaka Vyadhi* include both dietary and lifestyle causes that aggravate *Vata* and *Kapha*. Excessive consumption of dry, cold, and light foods, irregular diet patterns, excessive exposure to cold wind, dust, and improper scalp hygiene are primary contributors. Psychological factors like stress, anxiety, and suppression of natural urges also disturb the homeostasis of *Doshas*, aggravating scalp disorders.[14]

***Samprapti* (Pathogenesis)**

Due to continuous exposure to causative factors, *Vata* and *Kapha* get vitiated and localize in the scalp skin. The dry and rough qualities of *Vata* lead to dryness and fissuring, while the heavy and sticky properties of *Kapha* cause scaling and flaking. The *Dushyas* involved include *Twak* (skin), *Rakta* (blood), *Lasika* (lymph), and *Kesha* (hair). The affliction of these elements leads to the full manifestation of the disease, presenting with hallmark symptoms of dandruff.[15]

***Nidana Sevana* (Causative Factors)[16]**

↓

Vata-Kapha Dosha Prakopa (Aggravation of *Vata* & *Kapha*)

↓

Srotodushti (Obstruction in *Romakupa Srotas*)

↓

Dosha-Sanchaya in *Keshabhoomi* (Scalp region)

↓

Dushya Involvement:

- *Twak* (Skin)
- *Rakta* (Blood)
- *Lasika* (Lymph)
- *Kesha* (Hair)

↓

Agni Dushti (*Bhrajaka Pitta* impairment)

↓

Manifestation of Symptoms:

- *Kandu* (Itching)
- *Twak Rookshata* (Scalp dryness)
- *Twak Sphutana* (Scalp cracking)
- *Keshachyuti* (Hair fall)
- Scaling & flaking

Table 1: *Samprapti Ghataka*

Components	Details
Dosha	*Vata*, *Kapha*
Dushya	*Twak*, *Rakta*, *Lasika*, *Kesha*
Agni	*Bhrajaka Pitta* (local *Agni*)
Srotas	*Romakupa*, *Twak Srotas*
Udbhavasthana	*Twak* (scalp skin)
Adhisthana	*Kapala* (scalp)
Vyadhi Swabhava	*Krchrasadhya* (difficult to cure if chronic)

***Poorvarupa* (Prodromal Symptoms)[17]**

- Mild dryness of the scalp
- Occasional itching
- Fine scaling
- Roughness of hair texture

***Rupa* (Cardinal Signs & Symptoms)[18]**

1. *Kandu* (itching of the scalp)
2. *Twak Rookshata* (dryness of scalp)
3. *Twak Sphutana* (cracking/fissuring of scalp skin)
4. *Keshachyuti* (hair fall)
5. Scalp scaling (flaking)

Types- Although no specific types are described classically, *Darunaka* may present as:

- **Dry Type:** Dominant *Vata*, with excessive dryness, cracking, and sparse scaling.
- **Oily Type:** Dominant *Kapha*, with oily scalp, stickiness, and heavy scaling.

Correlation with Modern Diseases

In modern clinical practice, *Darunaka* can be correlated with dandruff (pityriasis capitis) and, when chronic and severe, with seborrheic dermatitis of the scalp. Both conditions are characterized by excessive scaling, itching, and sometimes erythema or inflammation of the scalp skin, though dandruff is typically non-inflammatory.[19]

***Chikitsa Sutra* (Line of Treatment)**

1. ***Vata-Kapha Shamana Chikitsa***
   - Use of *Snigdha* (unctuous), *Ushna* (hot), *Katu-Tikta-Kashaya Rasa* herbs.
2. ***Bahya Chikitsa* (External Therapies)**
   - *Taila Abhyanga* (oil application): Using oils like *Khasa Beeja Taila*, *Nimba Taila*, *Karanja Taila*.
   - *Lepa* (pastes): Application of medicated pastes on the scalp.
   - Shampoo with herbal decoctions: *Nimba*, *Khadira*, *Aragwadha* decoctions.
3. ***Shodhana Chikitsa* (Purification Therapies)**
   - *Vamana* in *Kapha* predominant conditions.
   - *Virechana* in *Pitta-Vata* involvement.
   - *Nasya Karma* for scalp-related conditions.
4. ***Shamana Chikitsa* (Palliative Therapies)**
   - Use of *Kashaya, Taila, Ghrita* preparations that are *Kapha-Vatahara*.

***Pathya-Apathya* (Dietary & Lifestyle Modifications)**

Pathya

- Warm, oily, and easily digestible food.
- Regular scalp hygiene with herbal oils.
- Avoiding cold exposure to the scalp.

Apathya

- Excessive intake of dry, cold, and stale food.
- Mental stress, irregular sleeping habits.
- Excessive washing of hair with harsh chemicals.

***Sadhyasadhyata* (Prognosis)**

Darunaka Vyadhi is generally *Sadhya* (curable) in its initial stage with proper intervention. However, if neglected, it can become *Kricchra Sadhya* (difficult to treat), especially in cases with chronic dryness, persistent dandruff, or associated scalp infections.[20]

Drug Review

Table 2: *Khasa Beeja Taila* (seed oil of *Papaver somniferum Linn.*)[21]

Aspect	Details
Botanical Name	*Papaver somniferum Linn.*
Common Names	Poppy Seed, *Khasa Beeja*, *Ahiphena Beeja*
Family	Papaveraceae
Part Used	*Beeja* (Seeds)
Method of Preparation	Cold-pressed oil extraction without heat.

Classical References

- *Acharya Sharangadhara* has mentioned *Khasa Beeja Kalka* application with *Godugdha* for *Darunaka Vyadhi*.
- *Bhavaprakasha* and other Ayurvedic texts recognize *Khasa Beeja* for conditions involving *Vata-Kapha* vitiation and scalp disorders.

Table 3: *Rasa Panchaka* (Pharmacodynamic Properties)[22]

Property	Details
Rasa	*Madhura, Kashaya*
Guna	*Guru, Snigdha*
Virya	*Ushna*
Vipaka	*Madhura*
Prabhava	*Vata-Kapha Shamaka*

Pharmacological Actions (As per Ayurveda)[23]

- *Vata-Kapha Hara*
- *Rukshata Hara* (alleviates dryness)
- *Kandu Prashamana* (relieves itching)
- *Tvak Sphutana Shamana* (reduces skin cracking)
- *Keshya* (promotes hair health and prevents hair fall)

***Khasa Beeja* Extraction of *Khasa Beeja Tailam* (seed oil of *Papaver Somniferum* Linn.)**

Figure 1: *Khasa Beeja* Extraction of *Khasa Beeja Tailam*

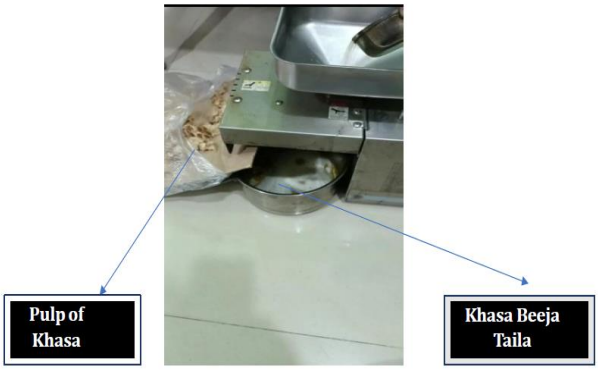


Figure 2: Extraction of oil

- The extraction of *Khasa Beeja Tailam* is a significant preparatory procedure involving the mechanical processing of *Khasa Beeja* (Papaver somniferum seeds) to obtain medicinal oil used in Ayurvedic therapeutics, especially for *Darunaka Vyadhi* (dandruff).
- In the initial stage, mature and dried *Khasa Beeja* seeds are collected and subjected to a cleaning

process to remove impurities such as dust, husks, and other extraneous materials. This ensures that only pure seeds are selected for oil extraction.

- Following the cleaning process, the seeds are subjected to cold-press mechanical extraction. The seeds are loaded into an oil expeller machine where mechanical pressure is applied to extract oil without the application of external heat, preserving the phytoconstituents that may degrade with heat exposure.
- The extracted oil is collected in a sterile container. The yield of oil from *Khasa Beeja* typically ranges between 30% to 50%, depending on the quality of seeds and efficiency of the mechanical expeller.
- Post-extraction, the oil is subjected to filtration to eliminate any remaining seed residues or impurities. This filtration process ensures the clarity and purity of *Khasa Beeja Tailam*.
- The filtered *Khasa Beeja Tailam* is then stored in sterile, airtight glass containers to preserve its potency and prevent oxidative degradation. Proper storage under controlled conditions is essential to maintain the therapeutic properties of the oil.
- This *Tailam* is then dispensed in standardized quantities, often in 30ml bottles, labeled with batch information, manufacturing date, and expiration details for clinical or therapeutic use.

Figure 3: Storage of Obtained and Filtered *Khasa Beeja Tailam and Khasa Beeja* Pulp

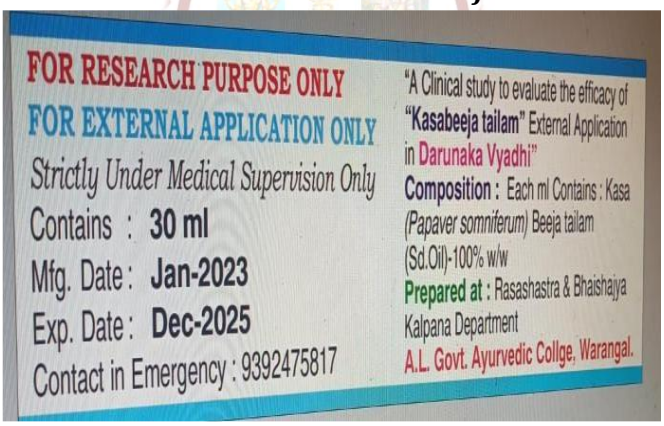


Figure 4: Label Used For 30ml Bottle

Figure 5: 30ml Bottles with Label Used for Dispensing of Medicine

Modern Phytochemical Profile[24]

- Rich in linoleic acid (70-73%), oleic acid (13-15%), palmitic acid (10-12.5%), stearic acid (1-2%), and tocopherols (vitamin E).
- Contains antioxidants and essential fatty acids that nourish and hydrate the scalp, support barrier repair, and exhibit mild anti-inflammatory properties.

Therapeutic Applications (Modern Correlation)

- Moisturizing the scalp and reducing dryness (*Keshabhoomi Rookshata*).
- Controlling flaking and scaling in dandruff conditions (*Twak Sphutana*).
- Reducing scalp itching (*Kandu*).
- Minimizing hair fall (*Keshachyuti*).
- Potential antimicrobial activity against *Malassezia* species implicated in dandruff.

Form of Administration

- External application of the seed oil directly on the scalp twice a week.

Safety Profile

- No significant adverse effects reported in the clinical study.
- No significant alterations in haematological parameters (CBP, ESR).

Figure no. 6 & 7

Figure no. 7 & 8

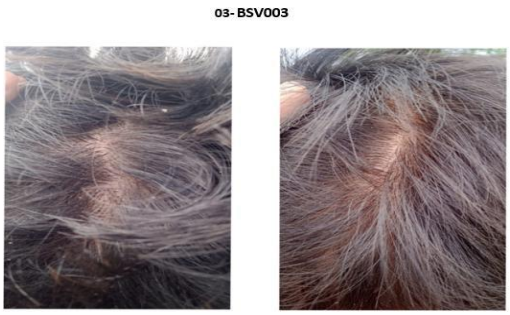


Figure no. 9 &10

Figure no. 11 & 12

05- BSN005

DAY-0 DAY - 4th week

Figure no. 13 & 14

06- SAR006

DAY-0 DAY - 4th week

Figure no. 15 & 16

07- RKP007

DAY-0 DAY - 4th week

Figure no. 17 & 18

08- MVS008

DAY-0 DAY - 4th week

Figure no. 19 & 20

09- TBD009

DAY-0 DAY - 4th week

Figure no. 19 & 20

11- BGT011

DAY-0 DAY - 4th week

Figure no. 23 & 24

12- BCN012

DAY-0 DAY - 4th week

Figure no. 25 & 26

13- RSK013

DAY-0 DAY - 4th week

Figure no. 27 & 28

14-BMH014

DAY-0 DAY - 4th week

Figure no. 29 & 30

15-GAP015

DAY-0 DAY - 4th week

Figure no. 31 & 32

16-KSB016

DAY-0 DAY - 4th week

Figure no. 33 & 34

17-RSH017

DAY-0 DAY - 4th week

Figure no. 35 & 36

18-PST018

DAY-0 DAY - 4th week

Figure no. 37 & 38

19-BRK019

DAY-0 DAY - 4th week

Figure no. 39 & 40

20-JMN020

DAY-0 DAY - 4th week

Figure no. 41 & 42

21-AHN021

DAY-0 DAY - 4th week

Figure no. 43 & 44

22-TSP022


DAY-0 DAY - 4th week

Figure no. 45 & 46

23-KAH023


DAY-0 DAY - 4th week

Figure no. 47 & 48

24-BVK024


DAY-0 DAY - 4th week

Figure no. 49 & 50

25-BSK025


DAY-0 DAY - 4th week

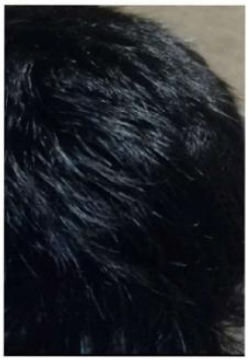
Figure no. 51 & 52

026-KGN026


DAY-0 DAY - 4th week

Figure no. 53 & 54

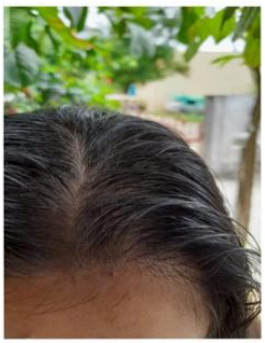
27-GKS027

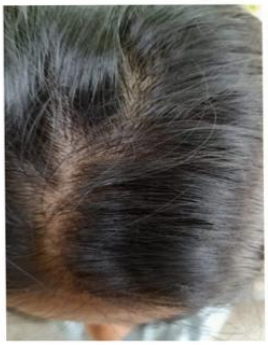



DAY-0 DAY - 4th week

Figure no. 55 & 56

28-RMN028





DAY-0 DAY - 4th week

Figure no. 57 & 58

29-SAL029

DAY-0 DAY - 4th week

Figure no. 59 & 60

30-JKM030

DAY-0 DAY - 4th week

Figure no. 61 & 62

OBSERVATION AND RESULT

Demographic Observations

Table 4: Total Registered Subjects

Category	Number of Subjects
Registered	30
Completed the Study	30
Dropouts	0

Table 5: Distribution According to Age

Age Group (Years)	Number of Subjects	Percentage (%)
18-20	1	3.33%
21-30	27	90.00%
31-40	2	6.33%
Total	30	100%

Table 6: Distribution According to Sex

Sex	Number of Subjects	Percentage (%)
Male	19	63.33%
Female	11	36.66%
Total	30	100%

Table 7: Distribution According to Marital Status

Marital Status	Number of Subjects	Percentage (%)
Married	3	10%
Unmarried	27	90%
Total	30	100%

Table 8: Distribution According to Education

Education Level	Number of Subjects	Percentage (%)
Uneducated	0	0%
Graduation	27	90%
Post-Graduation	3	10%
Total	30	100%

Table 9: Distribution According to Occupation

Occupation	Number of Subjects	Percentage (%)
Students	27	90%
Employees	3	10%
Total	30	100%

Table 10: Distribution According to Diet

Diet Type	Number of Subjects	Percentage (%)
Vegetarian	4	13.33%
Mixed	26	86.66%
Total	30	100%

Table 11: Distribution According to Sleep Pattern

Sleep Pattern	Number of Subjects	Percentage (%)
Samyaka (sound sleep)	30	100%
Asamyaka(disturbed sleep)	0	0%

Table 12: Distribution According to *Prakriti*

Prakriti	Number of Subjects	Percentage (%)
Vataja	10	33.33%
Pittaja	0	0%
Kaphaja	3	10%
Vatapittaja	10	33.33%
Pittakaphaja	7	23.33%
Kaphavataja	0	0%
Sama	0	0%
Total	30	100%

Table 13: Distribution According to Family History

Family History	Number of Subjects	Percentage (%)
Present	0	0%
Absent	30	100%

Table 14: Assessment of Adherent Scalp Flaking Score (ASFS)

Visits	Day 0	1 week	2 weeks	4 weeks
Mean	3.267	1.867	1.200	0.6000
Std. Deviation	2.132	1.737	1.540	1.192
Std. Error of Mean	0.3893	0.3171	0.2812	0.2176
Lower 95% CI of mean	2.470	1.218	0.6249	0.1549
Upper 95% CI of mean	4.063	2.515	1.775	1.045
p value	-	<0.0001	<0.0001	<0.0001
Significance	-	Highly significant	Highly significant	Highly significant

Table 15: Assessment of Pruritis Scale

Visits	Day 0	1 week	2 weeks	4 weeks
Mean	12.9	11.0	9.50	7.73
Std. Deviation	2.74	2.25	1.87	1.70
Std. Error of Mean	0.500	0.411	0.342	0.310
Lower 95% CI of mean	11.9	10.1	8.80	7.10
Upper 95% CI of mean	14.0	11.8	10.2	8.37
p value	-	<0.01	<0.001	<0.0001
Significance	-	Highly significant	Highly significant	Highly significant

Table 16: Assessment of *Keshabhoomi Rookshata*

Visits	Day 0	1 week	2 weeks	4 weeks
Mean	1.70	1.30	0.767	0.267
Std. Deviation	0.702	0.535	0.679	0.450
Std. Error of Mean	0.128	0.0977	0.124	0.0821
Lower 95% CI of mean	1.44	1.10	0.513	0.0987
Upper 95% CI of mean	1.96	1.50	1.02	0.435
p value	-	<0.01	<0.001	<0.0001
Significance	-	Significant	Very significant	Highly significant

Table 14: Assessment of *Kandu*

Visits	Day 0	1 week	2 weeks	4 weeks
Mean	1.43	1.13	0.633	0.400
Std. Deviation	0.679	0.730	0.718	0.563
Std. Error of Mean	0.124	0.133	0.131	0.103
Lower 95% CI of mean	1.18	0.861	0.365	0.190
Upper 95% CI of mean	1.69	1.41	0.902	0.610
p value	-	<0.01	<0.001	<0.0001
Significance	-	Significant	Significant	Highly significant

Table 16: Assessment of *Twak Sphutana*

Visits	Day 0	1 week	2 weeks	4 weeks
Mean	1.50	1.20	0.724	0.400
Std. Deviation	0.777	0.887	0.702	0.563
Std. Error of Mean	0.142	0.162	0.130	0.103
Lower 95% CI of mean	1.21	0.869	0.457	0.190
Upper 95% CI of mean	1.79	1.53	0.991	0.610
p value	-	<0.01	<0.001	<0.0001
Significance	-	Highly significant	Highly significant	Highly significant

Table 17: Assessment of *Keshachyuti*

Visits	Day 0	1 week	2 weeks	4 weeks
Mean	1.37	1.23	0.700	0.567
Std. Deviation	0.765	0.728	0.651	0.568
Std. Error of Mean	0.140	0.133	0.119	0.104
Lower 95% CI of mean	1.08	0.962	0.457	0.354
Upper 95% CI of mean	1.65	1.51	0.943	0.779
p value	-	<0.01	<0.001	<0.0001
Significance	-	Highly significant	Highly significant	Highly significant

Table 18: Assessment of Hemoglobin %

Visits	Day 0	4 weeks
Mean	11.4	11.5
Std. Deviation	1.74	1.57
Std. Error of Mean	0.319	0.287
Lower 95% CI of mean	10.7	10.9
Upper 95% CI of mean	12.0	12.1
p value	-	0.299
Significance	-	Not significant

Table 19: Assessment of Erythrocyte Sedimentation Rate (ESR)

Visits	Day 0	4 weeks
Mean	19.7	19.9
Std. Deviation	20.0	18.5
Std. Error of Mean	3.64	3.38
Lower 95% CI of mean	12.3	12.9
Upper 95% CI of mean	27.2	26.8
p value	-	0.811
Significance	-	Not significant

Findings of this Study

- *Khasa Beeja Taila* (seed oil of *Papaver somniferum* Linn.) demonstrated significant efficacy in the management of *Darunaka Vyadhi* (dandruff).
- There was a statistically significant reduction in Adherent Scalp Flaking Score (ASFS), indicating effective control of scalp flaking by the fourth week (*p <0.0001*).

- A consistent and progressive decrease was observed in pruritis (itching) assessed by the 5D Pruritis Scale, showing highly significant relief *(p <0.0001)*.
- Other clinical symptoms like *Keshabhoomi Rookshata* (scalp dryness), *Kandu* (itching), *Twak Sphutana* (cracking of scalp skin), and *Keshachyuti* (hair fall) showed substantial improvement with highly significant statistical outcomes.
- There was no significant change in hematological parameters such as hemoglobin % and ESR, confirming the safety of the external application of the oil.
- No adverse events or side effects were reported throughout the treatment period, establishing the safety profile of *Khasa Beeja Taila*.
- The oil exhibited *Vata-Kapha Shamana* action due to its *Madhura Rasa*, *Snigdha* and *Guru Guna*, providing a holistic Ayurvedic approach in managing *Darunaka*.
- Overall, *Khasa Beeja Taila* is effective, well-tolerated, and safe for the external treatment of dandruff, making it a promising Ayurvedic intervention for scalp health.

DISCUSSION

The present clinical study was conducted to evaluate the efficacy of *Khasa Beeja Taila* (seed oil of *Papaver somniferum* Linn.) in the management of *Darunaka Vyadhi*, which is closely related to dandruff in modern dermatology. *Darunaka* is described in Ayurvedic classics under *Kshudra Roga* and *Kapala Gata Roga*, characterized by symptoms like *Kandu* (itching), *Twak Rookshata* (scalp dryness), *Twak Sphutana* (cracking of the scalp), *Keshachyuti* (hair fall), and *Pidaka* (pustules) in some cases. The vitiation of *Vata* and *Kapha Dosha* is the primary pathology in *Darunaka*. The trial was designed as an open-label, single-arm study with 30 participants who applied *Khasa Beeja Taila* externally twice weekly for 4 weeks.[25]

In this study, significant improvement was observed in the Adherent Scalp Flaking Score (ASFS), where the mean score reduced from 3.267 at baseline to 0.600 by the fourth week, with a highly significant p-value <0.0001. This indicates that *Khasa Beeja Taila* has potent *Vata-Kapha Shamana* properties that helped in reducing the scaling and flaking of the scalp, which is a cardinal feature of *Darunaka*. The unctuous and lubricating nature of the oil possibly helped in counteracting the dryness of the scalp and minimized the accumulation of dead skin cells, hence reducing flake formation effectively.[26]

The 5D Pruritis Scale showed progressive reduction in pruritis from a mean score of 12.9 at baseline to 7.73 by the fourth week (p<0.0001). This reduction in itching suggests that the oil's *Snigdha* (unctuous) and *Madhura Rasa* (sweet taste) qualities soothed the irritated scalp and prevented further scratching, which often exacerbates the condition. The reduction in itching also prevented further mechanical damage to the scalp skin, supporting overall scalp health and reducing *Kandu*- an essential Ayurvedic symptom of *Darunaka*.[27]

Significant improvement was also noted in other clinical parameters such as *Keshabhoomi Rookshata* (dryness of scalp roots), *Kandu* (itching), *Twak Sphutana* (skin cracking), and *Keshachyuti* (hair fall). The mean scores for these parameters consistently reduced from baseline to the fourth week, each achieving a p-value <0.0001 in most parameters, indicating statistical significance. The unctuous nature of the oil not only provided moisture to the scalp but might have strengthened the hair roots, reducing hair fall significantly, a frequent complaint associated with *Darunaka Vyadhi*.[28]

In terms of safety, there was no significant change observed in hemoglobin levels (p=0.299) and ESR (p=0.811), and no adverse events were reported during the study. This indicates that *Khasa Beeja Taila* is safe for external application without any systemic side effects. The safety profile aligns with the traditional usage of poppy seeds in Indian households for dietary purposes, though the therapeutic application of its oil on the scalp is a novel approach validated through this study.[29]

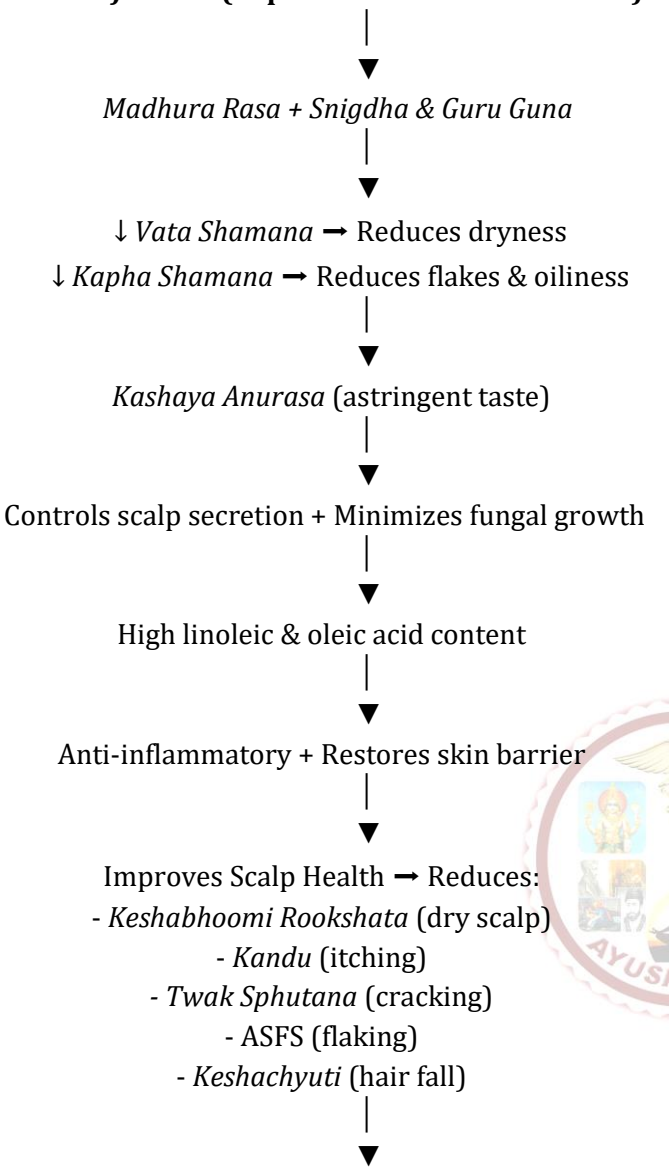
The probable Ayurvedic mode of action of *Khasa Beeja Taila* can be attributed to its *Madhura Rasa*, *Snigdha Guna*, and *Guru Guna*, which pacify *Vata* and *Kapha*. Its *Kashaya Anurasa* (astringent secondary taste) supports *Kapha Shamana*, reducing scalp oiliness and fungal colonization. The results of this clinical trial confirm that *Khasa Beeja Taila* is effective in managing *Darunaka Vyadhi*, providing a classical yet novel Ayurvedic intervention for dandruff. However, larger sample studies, comparative trials with standard antifungal agents, and longer duration studies are recommended to further establish its clinical efficacy and safety.[30]

Mode of Action of *Khasa Beeja Taila* in *Darunaka Vyadhi*

In the phase of this clinical trial, it was noticed that *Khasa/Ahiphena beeja tailam* can be from the seeds extracted by compression method. The yield varies from 30%-50%. The probable mode of action on *Darunaka* is *Vatakaphahara karma*. By its *Madhura rasa, Madhura vipaka, Guru guna* it is best *Vatahara dravya* along with its *Kashaya rasa* it also having *Kaphahara karma*. Dryness of scalp may be reduced by

the unctuousness of the drug and excessive proliferation of skin upper layers may be suppressed by the oil, thus controlling flaking of the scalp skin.[31]

***Khasa Beeja Taila* (Papaver somniferum Seed Oil)[32]**



Overall Management of *Darunaka Vyadhi*

Scope for Further Study

- *Khasa/Ahiphena beeja tailam* can be studied over larger sample size with placebo control for the validation of antidandruff activity.
- This drug can be studied over other parameters of dandruff like skin histopathology etc.
- This drug can be studied with standard anti-fungal drugs.
- Dose dependent studies can be planned in future.

CONCLUSION

The present clinical study concluded that *Khasa Beeja Taila* (seed oil of *Papaver somniferum* Linn.) is an effective and safe external application for the management of *Darunaka Vyadhi* (dandruff). The intervention significantly improved clinical parameters such as Adherent Scalp Flaking Score (ASFS), pruritis, *Keshabhoomi Rookshata*, *Kandu*, *Twak Sphutana*, and *Keshachyuti*, with highly significant statistical outcomes ($p < 0.0001$). The unctuous, sweet, and heavy qualities of the oil helped pacify *Vata* and *Kapha*, the primary *Doshas* involved in *Darunaka*, effectively reducing scalp dryness, flaking, itching, and hair fall. The treatment was well tolerated with no adverse events or significant changes in hemoglobin and ESR levels, confirming its safety. Thus, *Khasa Beeja Taila* can be considered a promising Ayurvedic therapeutic option for dandruff, although further large-scale studies and comparative trials with standard treatments are recommended for broader clinical validation.

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