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AN OPEN LABEL COMPARATIVE TRIPLE ARM CLINICAL STUDY TO EVALUATE THE EFFICACY OF PRAPAUNDARIKADI TAILA PRATIMARSHA NASYA, SHIROABHYANGA AND A COMBINATION OF BOTH IN MANAGEMENT OF AKALA PALITAM (PREMATURE GRAYING OF HAIR)

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ABSTRACT

Premature graying affects approximately 27.3% of the population. Medically, it is defined as the onset of gray hair before the age of 20 in Caucasians, before 25 in Asians, and before 30 in individuals of African descent. In Ayurveda, this early onset of graying is referred to as Akala Palitam. The body's internal heat, or Dehoushma, along with aggravated Pitta, accumulates in the scalp region. This imbalance leads to the premature graying of hair before the natural aging process, a condition known as Akala Palitam. In modern medicine, dietary supplements are available to manage premature graying, but they often fall short of providing a complete solution. The most common temporary fix is the use of chemical hair dyes, which can worsen the condition over time due to their toxic ingredients. Frequent dyeing is associated with several side effects, including hair loss and various scalp and skin disorders. From an Ayurvedic perspective, premature graying is seen as a systemic imbalance rather than just an external issue. Ayurveda offers a holistic and natural approach to addressing this condition, often delivering effective results without the harmful side effects associated with modern chemical treatments. The present study is planned to evaluate the efficacy of *Prapaundarikadi Taila* in the management of *Akala Palitam* w.s.r. to premature greying of hair. A randomized open-labelled comparative clinical study will be conducted on 60 patients, divided equally into three groups of 20 patients each. Group A will receive *Prapaundarikaadi Taila Pratimarsha Nasya*, Group B will receive *Shiroabhyanga* and Group C contain both *Prapaundarikaadi Taila Pratimarsha Nasya* and *Shiroabhyanga* The study aims to provide scientific evidence regarding the comparative efficacy of these interventions and establish an effective Ayurvedic management protocol for premature greying of hair. **Methodology:** 60 patients of *Akala Palitam* will be selected on the basis of inclusion and exclusion criteria. All patients will be divided into three groups. Each group having 20 patients. Group A will receive *Prapaundarikaadi Taila Pratimarsha Nasya*, Group B will receive *Shiroabhyanga* and Group C contain both *Prapaundarikaadi Taila Pratimarsha Nasya* and *Shiroabhyanga*. Observations will be done on the basis of before, and after subjective and objective parameters.

KEYWORDS: *Pratimarsha Nasya*, premature greying of hair, *Akala Palitam*, *Shiroabhyanga*, *Prapaundarikaadi Taila*.

INTRODUCTION

Hair is far more than a cosmetic appendage — it is a dynamic, biologically active mini-organ that reflects the physiological, nutritional, and psychological status of an individual. Beyond its protective role for the scalp, hair holds profound socio-cultural significance, closely tied to

perceptions of youth, vitality, and self-image. Consequently, any visible alteration in hair colour or texture carries an impact that extends well beyond the follicle itself.

Graying of hair, or canities, is a universal marker of chronological aging, resulting from the progressive decline of melanocyte stem cells in the hair follicle bulge and reduced melanogenesis. However, when this process occurs well before its expected biological timeline, it is termed premature graying of hair -medically defined as onset before age 20 in Caucasians, before 25 in Asians, and before 30 in individuals of African descent. Once considered a phenomenon of the fifth decade of life, graying is now frequently reported in individuals in their twenties, and even late teens — a shift strongly correlated with contemporary lifestyle stressors: chronic psychological stress, oxidative burden, nutritional deficiencies (particularly of vitamin B12, iron, and copper), disturbed sleep, exposure to environmental pollutants and chlorinated water, and heightened use of chemical hair products.

Epidemiological data underscore the scale of the problem, with premature graying reported in nearly 27.3% of the population, and its psychosocial toll — diminished self-esteem, social anxiety, and impaired quality of life — is increasingly documented in dermatological and psychological literature.

Modern medicine currently offers no definitive curative approach to PGH. Management remains largely cosmetic — chemical hair dyes being the mainstay — despite growing evidence linking their prolonged use to allergic dermatitis, follicular damage, and paradoxical acceleration of hair fall and graying. This therapeutic gap creates a compelling rationale for exploring safer, mechanistically holistic alternatives.

Ayurveda, interestingly, recognized this condition several millennia ago as *Akala Palitam* — literally, "graying before its time." Classical texts attribute its pathogenesis to the vitiation of *Pitta Dosha* and aggravated *Dehoshma* (endogenous metabolic heat) localized at the scalp, which "cooks" or degrades the pigment-bearing structures of hair, consistent conceptually with the oxidative-stress-driven melanocyte damage described in modern trichology. This parallel between an ancient humoral model and contemporary free-radical biology lends *Akala Palitam* particular relevance as a subject for integrative scientific inquiry.

Among Ayurveda's therapeutic repertoire for *Urdhvajatrugata Vyadhis* (diseases above the clavicle), *Nasya Karma*- nasal instillation of medicated oils — occupies a privileged position, owing to the nasal cavity's direct anatomical continuity with the cranial cavity via the cribriform plate. *Pratimarsha Nasya*, its mildest and most sustainable form, is well suited for long-term daily use and is specifically indicated for disorders of the scalp and hair. Complementing this, *Shiroabhyanga* — therapeutic head massage — enhances local microcirculation, reduces cortisol-mediated stress, and nourishes the hair follicle through both mechanical and neuro-hormonal pathways.

Prapaundarikadi Taila, a classical formulation described in the *Ashtanga Hridaya*, combines *Rasayana* (rejuvenative) herbs in a *Tila Taila*(sesame oil) base and is specifically indicated for *Palitam*. Despite its explicit classical indication, no study to date has independently compared the efficacy of this formulation when administered via *Nasya*, *Shiroabhyanga*, and their combination — representing a clear research gap.

This study, therefore, seeks to scientifically evaluate and compare the efficacy of *Prapaundarikadi Taila Pratimarsha Nasya, Shiroabhyanga*, and their combined application in the management *of Akala Palitam*, with the aim of generating clinical evidence for a safe, non-invasive, and mechanistically rational Ayurvedic alternative to current cosmetic management strategies.

Objectives

1. To evaluate the efficacy of *Prapaundarikadi Taila Pratimarsha Nasya* in management of *Akala Palitam*.
2. To evaluate the efficacy of *Prapaundarikadi Taila Shiroabhyanga* in management of *Akala Palitam*.
3. To evaluate the efficacy of both *Pratimarsha Nasya* and *Shiroabhyanga* in management of *Akala Palitam*.
4. To compare the efficacy of *Partimarsha Nasya*, *Shiroabhyanga* and a combination of both in management of *Akala Palitam.*

Research Question

Whether the combination of *Prapaundarikadi Taila Pratimarsha Nasya* and *Shiroabhyanga* is more effective than their individual application in management of *Akala Palitam* (Premature graying of hair)?

Hypothesis

Null Hypothesis (H_0)

There is no difference in the effect of the combination of *Prapaundarikadi Taila Pratimarsha Nasya* and *Shiroabhyanga* compared to their individual application in the management of *Akala Palitam*.

Research Hypothesis (H_1)

There is difference in the effect of the combination of *Prapaundarikadi Taila Pratimarsha Nasya* and *Shiroabhyanga* compared to their individual application in the management of *Akala Palitam.*

MATERIAL AND METHODS

Study Design

Type of Trial: Interventional
Design: Randomized clinical trial
Purpose: Treatment
Masking: No, Open Labelled
Timing: Prospective

Endpoint: Efficacy and safety
Duration of trial: 18 months
Phase of trial: Phase 2
Subjects: 60 (20 in each group)
No of group: 3
Statistical tool: Appropriate tool will be applied
Selection of Patients: A total of 60 patients meeting the inclusion criteria were selected for the study.

Inclusion Criteria
1. The patient between the age group of 20-30 year of both sexes.
2. Patient having feature of *Akala Palitam* as per Ayurvedic and modern literature (Premature graying of hair).
3. Consent obtained from respective patient.
4. Patient indicated for *Pratimarsha Nasya Karma* and *Shiroabhyanga*.

Exclusion Criteria
1. Patient of age below 20 years and above 30 years of either sex.
2. History of congenital or hereditary gray hair.
3. Scalp infections or dermatological conditions affecting the scalp or hair (e.g., psoriasis, eczema, severe dandruff).
4. Presence of any chronic systemic illness, such as: (Hypothyroidism or hyperthyroidism Vitiligo, Diabetes mellitus, Severe anemia, Autoimmune disorders)
5. Patient contraindicated for *Pratimarsha Nasya Karma* and *Shiroabhyanga*.
6. Use of hair dyes, chemical treatments, or hair colouring products in the past 3 months.
7. Addiction to smoking, alcohol, or other drugs which may influence hair pigmentation.

Sources of Data
Literature Source: The literature related to disease, and the formulation will be reviewed from *Samhitas*, contemporary system of medicine textbook, published articles, research journals and relevant websites.[8]

Clinical Source: Daily OPD, patients of Institute for Ayurved Studies & Research Hospital, Kurukshetra & patients diagnosed *akal palitam* will be considered for the study after obtaining written informed consent.

Experimental Source: This was a human clinical study, no animal experimentation was conducted.

Interventions

S.n.	Group	Intervention *(Prapaundarikadi Taila)*	Route of Administration	Dose	No. of patients	Duration
1.	Group A	*Pratimarsha Nasya*	Per Nasal	2 *bindu* (1ml) each nostril BD	20	60 days
2.	Group B	*Shiroabhyanga*	Local application	5 ml for 5 minutes OD	20	60 days
3.	Group C	*Pratimarsha Nasya* with *Shiroabhyanga*	Per Nasal and Local application	2 *bindu* (1ml) each nostril BD and 5 ml for 5 minutes OD.	20	60 days

Route of Administration: Local application

Method of Preparation
Prapaundarikadi Taila will be made according to the *taila Kalpana* method mentioned in *Sharangdhar Samhita*.
Follow up: The duration of the trial will be 90 days.
(During Treatment i.e., 0 to 60 Days - Follow up will be Day 30th, Day 60th)
(After Treatment i.e., 60 to 90 Days - Follow up will be Day 75th, Day 90th)

Assessment Criteria
Subjective Parameters[10]
1. *Akala kesh vaivarnyata* (Colour of hair)
2. *Rooksha sphutitha* (Dry splitted hair)
3. *Snigdha sthool* (Oiliness)
4. *Daha* (Burning sensation of scalp)

Objective Parameters[11]
- GSS (Graying severity score)

Outcomes
Primary
Reduction in the count of Gray Hairs/cm^2

Secondary
Improvement in Symptoms such as Colour of hair, Dry split hair, Oiliness, Burning Sensation of scalp.

Sample Size
The formula is:

$$n = \left\lceil \frac{Z_{1-\alpha/2}\sqrt{p_0(1-p_0)} + Z_{1-\beta}\sqrt{p_1(1-p_1)}}{p_1 - p_0} \right\rceil$$

Where:

- p_1 = **expected new treatment response rate**
- p_0 = **cure rate** (historical control or baseline rate)
- $Z_{1-\alpha/2}$, $Z_{1-\beta}$ = standard normal deviates for significance and power respectively.

Sample size according to this formula come out to be 62, but considering the drop out factor of the patient, 20 cases in each group will be taken.

Ethical clearance & CTRI Registration

The study was registered with the Clinical Trials Registry of India (CTRI) with **CTRI NO. CTRI/2025/08/093530.**

OBSERVATIONS AND RESULTS

The results were evaluated based on the predefined assessment criteria and statistically analysed for significance.

DISCUSSION

The obtained results will be discussed on the basis of Ayurvedic concept and modern parameters.

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