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EFFECT OF BHRINGRAJ TAILA NASYA COMBINED WITH SHIRO ABHYANG OF KAYYONYADI TAILA IN THE MANAGEMENT OF PALITYA (PREMATURE CANITIES): PROTOCOL FOR A RANDOMISED, OPEN-LABELLED CLINICAL STUDY

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ABSTRACT

Background: : Palitya, the Ayurvedic term for premature hair graying, is categorised within classical texts as a Kshudraroga arising chiefly from vitiated Pitta dosha. Contemporary observations place the typical age of onset before 20 years among individuals of European ancestry, before 25 years in Asian populations, and before 30 years in those of African descent, and the disorder appears to be growing more common among younger adults, a shift generally linked to changing dietary habits, lifestyle pressures, and environmental exposures. Because graying carries visible cosmetic weight and can erode self-confidence, the search for interventions that are both effective and low-risk remains a genuine public-health concern. Nasya karma, one of the Panchakarma procedures reserved for disorders of the Urdhwajatrugata (supraclavicular) region, and Shiro Abhyang, or therapeutic head-oil massage, are both classically prescribed for conditions of the scalp and hair.

Objective: This article sets out the protocol for a planned two-arm, randomised, open-labelled controlled clinical study that will examine whether Bhringraj Taila administered by Nasya, alongside Shiro Abhyang with Kayyonyadi Taila, offers benefit in the management of Palitya, with particular focus on premature canities.

Methods: The trial is structured as a parallel-group, randomised, open-labelled study to be carried out across the outpatient and inpatient services of the Department of Shalakyatantra at a government Ayurveda teaching hospital. A total of 168 eligible participants (84 per arm, a figure that already accounts for an anticipated 20% attrition) between the ages of 18 and 45 years, presenting with mild to moderate graying (5–15% gray hair on trichoscopic evaluation), will be randomly allocated to either a study arm receiving Bhringraj Taila Nasya (delivered as Pratimarsha Nasya, three drops twice daily) together with Kayyonyadi Taila Shiro Abhyang on alternate days, or a control arm receiving Kayyonyadi Taila Shiro Abhyang alone on alternate days; both regimens will run for 90 days. Grey-hair burden, expressed as the percentage of gray hair per unit scalp area across five scalp zones, constitutes the primary outcome and will be measured by trichoscopy at baseline and again on days 30, 60, and 90, with a post-treatment review at day 120. Routine haematological and biochemical testing will be used to monitor safety throughout the study period.

Expected Outcome: This study is anticipated to yield clinical evidence comparing the efficacy and safety of combined Nasya–Abhyang therapy against Shiro Abhyang used alone for arresting or reversing premature canities, thereby adding to the limited pool of Ayurvedic and integrative treatment options available for a condition that conventional medicine has yet to address with strong therapeutic solutions.

Keywords: Palitya; premature canities; Bhringraj Taila; Kayyonyadi Taila; Nasya karma; Shiro Abhyang; Ayurveda; randomised controlled trial; protocol

1. INTRODUCTION

Palitya, the classical designation for premature graying of hair, appears under the heading of Kshudraroga in the Sushruta Samhita (Nidana Sthana, Shiropratishedha Adhyaya) and receives similar treatment in the Ashtanga Hridaya.

Graying that accompanies normal aging is, of course, an expected physiological change, yet its early onset — a pattern increasingly linked to present-day lifestyle habits and environmental pressures — has come to represent a notable cosmetic and psychological burden, especially for younger adults. Epidemiological figures cited in the research proposal underlying this study, drawn from World Health Organization–referenced criteria, indicate that premature graying occurs most frequently in the 20–35 year age bracket, typically beginning before age 20 in Caucasian populations, before 25 in Asian populations, and before 30 among individuals of African descent

Ayurveda organises its clinical scope into eight branches, collectively termed Ashtanga Ayurveda, among which Shalakyatantra is devoted to disorders of the sense organs — the head, ear, nose, eye, and throat. Nasya karma ranks among the principal therapeutic approaches recommended for Urdhwajatrugata disorders, on the reasoning that the nasal passage offers a direct route to structures at the base of the skull. Pharmacologically, the dense vascular supply of the nasal mucosa and the olfactory region's close proximity to the central nervous system have been proposed as mechanisms that could support both systemic and, potentially, central drug delivery — offering a plausible biological rationale for Nasya's classical use in head disorders.

Because gray hair is widely read as a sign of aging, its premature appearance can take a toll on self-esteem and social confidence. Classical Ayurvedic literature lists numerous single herbs and compound formulations valued for Keshya (hair-nourishing) and Keshranjana (hair-darkening) properties, yet robust, comparative clinical data supporting these formulations remain scarce. This protocol was accordingly developed to build structured clinical evidence around two such preparations — Bhringraj Taila, given via the nasal route, and Kayyonyadi Taila, applied as a head massage.

2. RATIONALE AND PURPOSE OF THE STUDY

Community-based estimates suggest that a considerable share of the Indian population — by some accounts, as much as 60–70% — experiences Palitya to some degree, a condition that Ayurvedic pathophysiology attributes mainly to vitiated Pitta dosha, worsened further by present-day dietary and lifestyle patterns. Classical compendia such as the Bhaishajya Ratnavali describe several Kshudraroga formulations intended for this condition. Given this textual foundation and the scarcity of proven, low-risk therapeutic options within conventional medicine, the present study was designed to determine whether Nasya karma using Bhringraj Taila, in combination with Shiro Abhyang using Kayyonyadi Taila, produces measurable benefit — with the wider goal of contributing an evidence-based, cost-effective intervention to public health practice.

3. RESEARCH QUESTION AND HYPOTHESES

3.1 Research Question

Does Bhringraj Taila Nasya (three drops twice daily), given together with Kayyonyadi Taila Shiro Abhyang on alternate days, produce a beneficial effect in the management of Palitya ?

3.2 Hypotheses

- Null hypothesis (H0): Bhringraj Taila Nasya combined with Kayyonyadi Taila Shiro Abhyang, administered as described, does not produce a beneficial effect on premature canities.

- Alternative hypothesis (HA): Bhringraj Taila Nasya combined with Kayyonyadi Taila Shiro Abhyang, administered as described, produces a beneficial effect on premature canities.

4. AIM AND OBJECTIVES

4.1 Aim

To assess the effect of Bhringraj Taila Nasya combined with Shiro Abhyang of Kayyonyadi Taila in the management of Palitya, with particular reference to premature canities.

4.2 Objectives

Primary objective

- To examine the effect of Bhringraj Taila Nasya combined with Kayyonyadi Taila Shiro Abhyang in the management of Palitya.

Secondary objectives

- To explore the relationship between doshaj Prakriti (constitutional type) and the presentation of Palitya.

- To document the adverse-effect profile associated with Bhringraj Taila Nasya combined with Kayyonyadi Taila Shiro Abhyang.

5. STUDY DESIGN

This is a prospective, randomised, open-labelled, two-arm, parallel-group controlled clinical trial. The overall workflow begins with identification and authentication of the raw drugs, proceeds through standardised preparation of the two study oils and their physicochemical characterisation, and then moves into the clinical study proper, followed by data collection, statistical analysis, discussion, and conclusion.

Type of study: Randomised, open-labelled, controlled clinical study.

Setting: Outpatient (OPD) and inpatient (IPD) services of the Department of Shalakyatantra, Government Ayurved College & Hospital, Nanded.

Duration: Governed by the institutional Ph.D. course schedule, with an overall project timeline of June 2021 to June 2027 and a clinical trial/data-collection phase spanning April 2022 to December 2026.

6. PREPARATION OF STUDY DRUGS

Both trial oils will be prepared in-house following the Taila Nirmana Vidhi (the standard oil-preparation method) as described in the Sahasrayogam, Taila Prakarana, and will be subjected to physicochemical analysis before being used clinically.

6.1 Bhringraj Taila

Ingredient	Quantity
Bhringraj (Eclipta alba) Swarasa (juice)	1500 ml
Til Taila (sesame oil)	187 ml
Godugdha (cow's milk)	1500 ml
Yashtimadhu Kalka (paste)	46 g

6.2 Kayyonyadi Taila

Ingredient	Quantity
Kayyonni / Bhringraj (Eclipta alba) juice	1.024 L
Guduchi (Tinospora cordifolia) decoction	1.024 L
Amalaki (Emblica officinalis) juice extract	1.024 L
Til Taila (sesame oil)	768 ml
Godugdha (cow's milk)	768 ml
Yashtimadhu	48 g
Anjana / Daru Haridra (Berberis aristata)	48 g

7. CLINICAL STUDY PROTOCOL

7.1 Overview

Participants presenting to the OPD and IPD of the Department of Shalakyatantra will first be screened for eligibility. Written informed consent will be taken once counselling has been provided, and a skin-sensitivity test will be carried out at the screening visit. Participants who are eligible and willing to enrol will then be randomised in a 1:1 ratio, using a computer-generated randomisation list, into one of two parallel arms.

Group	Allocation	Intervention
Group A	Study group	Bhringraj Taila Nasya, three drops per nostril twice daily (administered as Pratimarsha Nasya), combined with Kayyonyadi Taila Shiro Abhyang on alternate days, for a total of 90 days
Group B	Control group	Kayyonyadi Taila Shiro Abhyang alone, applied on alternate days, for 90 days

7.2 Sample Size

Sample size was calculated using Daniel's (1999) formula for a single population proportion, taking an assumed prevalence of premature graying of 27% and an allowable error of 10% of that prevalence estimate, at a 95% confidence level (Z = 1.96). This calculation yielded a requirement of approximately 140 participants; after building in an anticipated 20% dropout rate, the target enrolment was set at 168 participants overall — that is, 84 per group, comprising 70 evaluable participants plus a 14-participant dropout allowance in each arm.

7.3 Eligibility Criteria

Inclusion criteria

- Age 18–45 years, either sex.
- Haemoglobin greater than 7 g%.
- Mild to moderate hair graying (5–15% gray hair), confirmed through dermatologist evaluation and microphotographic/trichoscopic image analysis.
- Willingness to provide informed consent and to comply with the study protocol.
- Willingness to attend all scheduled follow-up visits.

Exclusion criteria

- Severe hair fall or graying secondary to a clinically significant disorder (e.g., anemia, thyroid disease).
- Severe scalp dermatological disorders likely to confound assessment.
- Recent illness such as malaria, typhoid, or jaundice, or other scalp disease; or a judgment of ineligibility by the investigator.
- Use of hair dye or colorants within the preceding 6 months.
- Current immunosuppressive therapy or chemotherapy.
- History of hair transplantation.
- Systemic steroid use exceeding 14 days within the 2 months preceding enrolment.
- Known hypersensitivity to any constituent of the study oils.
- Pregnancy, planned pregnancy, or lactation.
- Structural nasal pathology (deviated nasal septum, furuncle, polyp, neoplasm, septal haematoma or perforation) or nasal infection (bacterial, viral, or atrophic rhinitis), or the presence of a nasal foreign body.
- Uncontrolled systemic disease (e.g., diabetes mellitus, hypertension, ischaemic heart disease) or other organic/infectious illness.
- Congenital anomalies of the nose or adjoining structures.

Withdrawal criteria

- Occurrence of a serious adverse event.
- Development of any other systemic complication.
- Participant unwillingness to continue, or to adhere to the assessment schedule.
- Withdrawal of consent by the participant.
- Any intercurrent illness likely to interfere with assessment of drug efficacy.
- Protocol violation or participant non-cooperation.

7.4 Intervention Procedures

Nasya: This will be administered as Pratimarsha Nasya, a nasal-oil procedure that, according to classical description, may be given regardless of age or season and without the preparatory (Purvakarma) or post-procedural (Paschatkarma) steps typically required for more intensive forms of Nasya. Participants in the study group will receive three drops of Bhringraj Taila in each nostril, twice daily, followed by a lukewarm-water Gandusha (oral rinse) as the Paschatkarma measure.

Shiro Abhyang: Participants in both arms will self-apply roughly 5–10 ml of Kayyonyadi Taila to the scalp, using either an applicator or the fingertips, on alternate days.

7.5 Visit Schedule and Assessments

At the baseline visit (Day 0), each participant will undergo a general physical examination, Ashtavidha Pariksha and other Ayurvedic clinical assessments, and baseline trichoscopic quantification of gray hair across five scalp zones — frontal, vertex, temporal right, temporal left, and occipital — recorded as the percentage of gray hair per cm^2 in each zone. Participants will then be reviewed at 15-day intervals, with formal efficacy assessments carried out on Days 30, 60, and 90, followed by a medication-free assessment at Day 120 to gauge the durability of any observed effect. At every visit, participants will undergo general and systemic examination, a review of clinical symptoms, and a questionnaire-based evaluation covering related hair parameters such as hair fall, dandruff, and growth. Both the participant and the investigator will record an overall assessment of change in hair colour at Days 30 and 90. At the concluding visit (Day 90), safety and tolerability will be evaluated jointly by investigator and participant, study medication will be stopped, and participants will move on to standard advice.

7.6 Laboratory and Diagnostic Investigations

- Complete blood count (CBC)
- Random blood sugar level (BSL-R)
- Thyroid function test
- Serum vitamin B12
- Trichoscopy (the principal diagnostic and outcome-assessment tool)

7.7 Outcome Measures

Primary outcome: The change from baseline in percentage of gray hair per cm^2, measured by trichoscopy across the five predefined scalp zones, at Days 30, 60, 90, and 120.

Secondary outcomes: The relationship between doshaj Prakriti and disease presentation; participant- and investigator-rated global assessment of hair colour change; questionnaire-based evaluation of hair fall, dandruff, and hair growth; the frequency and character of adverse events; and the overall tolerability and safety of both interventions.

Scalp zone	Baseline (Day 0)	Day 30	Day 60	Day 90	Day 120
Frontal					
Vertex					
Temporal (right)					
Temporal (left)					
Occipital					

Table: Trichoscopic gray-hair assessment record (percentage gray hair per cm^2 by scalp zone and visit).

7.8 Safety Monitoring

Every participant will be observed for adverse events from the baseline visit through to the end of the study. Any adverse event that occurs will be documented, assessed by the investigator, and managed in line with standard clinical practice; participants may be withdrawn from the study should a serious adverse event or a significant systemic complication arise.

7.9 Statistical Analysis

Data will be analysed without regard to sex, religion, socio-economic status, or occupation, applying a 95% confidence level (5% level of significance) throughout. The Z-test will be applied to objective (quantitative) parameters and the chi-square test to subjective (categorical) parameters; where parametric assumptions are not met, the Wilcoxon signed-rank test and the Mann–Whitney U test will be used for the relevant subjective parameters.

8. ETHICAL CONSIDERATIONS

This protocol has been reviewed and approved by the Institutional Ethics Committee of Government Ayurved College, Nanded, which confirmed that both the title and the synopsis do not duplicate prior work and that the research guide holds current university recognition. Written informed consent will be secured from every participant before enrolment, using a bilingual (English and Marathi) participant information sheet and consent form. Participants will be made aware of their right to withdraw at any point without affecting their ongoing care, as well as of the confidentiality protections applied to their data. Those who decline to enrol, or who later withdraw, will be offered the standard treatment available at the hospital.

9. DISCUSSION

This protocol brings together two classically described interventions for disorders of the head and hair — Nasya karma, broadly indicated for Urdhwajatrugata disorders, and Shiro Abhyang, a widely practised palliative measure for scalp and hair conditions — into a single combined regimen for premature canities, and evaluates this combination against Shiro Abhyang used alone. Earlier published work on comparable Nasya-based regimens for Akala Palitya has generally reported modest, gradual improvement that tends to become apparent only toward the close of a 90-day treatment course, together with a recognised role for diet, lifestyle, and psychological factors in shaping disease course. Separate studies focused specifically on Kayyonyadi Taila as Shiroabhyanga have described it as an effective palliative measure, an effect attributed to properties said to aid Sneha penetration into the scalp and to pacify aggravated Pitta and Vata dosha. The present design extends this body of literature by incorporating a standardised, trichoscopy-based quantitative outcome measure, a pre-calculated sample size, formal randomisation, and a post-treatment follow-up period — addressing methodological gaps, namely small sample sizes and short follow-up durations, noted in some earlier studies of this condition.

10. CONCLUSION

Premature graying of hair remains a common cosmetic concern for which conventional medicine offers few proven treatment options, even as Ayurvedic literature has long proposed a range of remedies. This protocol outlines a randomised, open-labelled, controlled clinical study intended to generate structured, quantitative evidence on the effect of Bhringraj Taila Nasya combined with Kayyonyadi Taila Shiro Abhyang, compared against Shiro Abhyang alone, in managing Palitya. The completed trial is expected to clarify the comparative efficacy, safety, and durability of this combined Ayurvedic regimen and to inform future research and clinical practice in this area.

11. TRIAL STATUS AND DECLARATIONS

Registration: Registered with the Maharashtra University of Health Sciences, Nashik.

Funding: Institutional (Government Ayurved College & Hospital, Nanded), conducted as part of the Ph.D. programme in Shalakyatantra.

Conflicts of interest: None declared.

Ph.D. Scholar: Vd. Chavan Pallavi Gulabsingh; Research Guide: Dr. A. B. Deshmukh, Professor, Department of Shalakyatantra, Government Ayurved College & Hospital, Nanded, under the Maharashtra University of Health Sciences, Nashik.

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