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Evaluation of Comparative Efficacy of Vamana Karma (Therapeutic Emesis) versus Virechana Karma (Therapeutic Purgation) in the management of Subclinical Hypothyroidism – A Study Protocol

[1]Dr Deepali Sherekar, [2]Dr Punam Sawarkar

[1] BAMS, MD(Panchakarma), Ph.D. scholar, Associate Professor, Department of Panchakarma, Government Ayurveda college, Vazirabad, Nanded, Nanded-Waghala, Maharashtra 431601,

ORCHID -0000-0002-8944-3320

[2]Associate Professor, Department of Panchakarma, Mahatma Gandhi Ayurveda College Hospital and Research Centre (MGACH&RC), Salod (Hirapur) Wardha, Maharashtra University: DMIMS, Sawai (Meghe) Wardha, Maharashtra,

Orchid id - 0000-0001-7980-7832

***Corresponding Author - Dr Deepali Sherekar**

Mahatma Gandhi Ayurveda College Hospital and Research Centre (MGACH&RC),

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ABSTRACT

Background: Subclinical hypothyroidism (SCH) is characterized by elevated serum thyroid-stimulating hormone (TSH) with normal free thyroxine (FT4) concentrations and has a reported prevalence of 6–15% in India. SCH is associated with increased cardiovascular risk and progression to overt hypothyroidism. Biomarker-based monitoring of thyroid function is central to clinical decision-making. Traditional Ayurvedic detoxification procedures, *Vamana* and *Virechana*, are proposed to modulate metabolic homeostasis; however, objective biomarker-based evaluation of their effects in SCH remains limited.

Objectives: To evaluate and compare the effects of *Vamana* and *Virechana* Karma on biochemical thyroid function markers in individuals with SCH.

Materials and Methods: This randomized pilot clinical study will enroll 30 participants with SCH, allocated into two intervention groups. Following standardized preparatory procedures (*Deepana-Pachana*, *Snehapana*, *Abhyanga*, *Swedana*), Group A will undergo *Vamana* (Madanaphala- pippali churna - 5gm+ Saindhav lavana - 1 gm+ Honey 10 gm formulation) and Group B will receive *Virechana* (Trivritta Leha). Serum TSH and FT4 levels will be quantified using validated immunoassay techniques at baseline, post-intervention, and at 3-month follow-up. Secondary outcomes include body mass index (BMI) and symptom scoring. Statistical analysis will assess within- and between-group differences. The study has received ethical approval and is registered with CTRI (CTRI/2022/12/047833).

Results: The study anticipates measurable modulation of TSH levels and stabilization of FT4 concentrations in both groups.

Conclusion: This study aims to provide biomarker-based evidence regarding the effects of

Vamana and *Virechana* in SCH. Findings may contribute to integrative approaches in thyroid disorder management.

Keywords: Subclinical hypothyroidism; Thyroid-stimulating hormone (TSH); Free thyroxine (FT4); Panchakarma; Vamana; Virechana

Introduction:

Background and Rationale

Subclinical hypothyroidism (SCH) is a biochemical condition characterized by elevated serum thyroid-stimulating hormone (TSH) levels in the presence of normal circulating free thyroxine (T4) concentrations. It represents an early or mild form of thyroid dysfunction and has emerged as a significant public health concern, particularly in countries such as India, where the prevalence ranges between 6% and 15%.[1,3,45] Epidemiological evidence indicates that India bears a disproportionately high burden of thyroid disorders compared to Western populations, with hypothyroidism affecting approximately 11% of adults.[3] The higher prevalence among women, middle-aged individuals, and those with increased body mass index (BMI) further accentuates its socio-clinical relevance.

Although SCH is frequently asymptomatic or minimally symptomatic, accumulating evidence suggests that it is not a benign entity. Studies have demonstrated its association with adverse cardiovascular outcomes, including heart failure, coronary artery disease, dyslipidemia, and increased cardiovascular mortality.[6,8,9] Furthermore, longitudinal data reveal that 2–6% of individuals with SCH progress annually to overt hypothyroidism, thereby increasing long-term morbidity.[6,8,16] Neurocognitive impairments, reduced functional capacity, and compromised quality of life have also been reported in affected individuals.[17,18] These findings highlight the importance of early identification and appropriate therapeutic intervention in the subclinical stage to prevent disease progression and systemic complications.

Levothyroxine replacement therapy is the standard treatment for overt hypothyroidism and is selectively recommended in SCH, particularly when TSH levels exceed 10 mIU/L or when cardiovascular risk factors are present.[5,12] However, the initiation of therapy in mild or borderline cases remains controversial. Evidence from community-based surveys indicates significant rates of overtreatment and undertreatment among patients receiving levothyroxine.[17] Additionally, a subset of patients continues to report persistent symptoms despite biochemical normalization.[49] Concerns regarding long-term adverse effects, including cardiac arrhythmias and reduced bone mineral density, further complicate therapeutic decision-making.[24] Consequently, there is a compelling need to explore alternative or complementary strategies that are safe, sustainable, and capable of addressing both metabolic dysfunction and systemic manifestations of SCH.

From an Ayurvedic perspective, thyroid disorders are broadly conceptualized under *Galaganda*.[34,35] The pathogenesis of SCH may be interpreted as a state of *Jatharagnimandya* and *Dhatwagnimandya*, predominantly involving vitiation of *Kapha* and *Vata* doshas in a background of *Bahudoshavastha*. The asymptomatic nature of SCH corresponds to *Avyakta avastha*, wherein pathological changes exist at the metabolic and tissue levels but are not fully manifested clinically. In such conditions, *Shodhana* (biopurificatory therapy) is considered

superior for eliminating accumulated doshas and restoring metabolic equilibrium [Charaka Samhita; Sushruta Samhita].[34-36]

Among Panchakarma procedures, *Vamana karma* (therapeutic emesis) and *Virechana karma* (therapeutic purgation) are classical detoxification techniques indicated in the management of disorders involving *Kapha* and *Pitta* predominance and in the treatment of *Galaganda*. While Vamana is traditionally regarded as highly effective in Kapha-dominant conditions, it is relatively intensive and may limit patient acceptance. Virechana, by contrast, is widely practiced due to its comparatively simpler execution and lower procedural discomfort. Despite their theoretical indications, there is a paucity of rigorously designed randomized controlled trials comparing the relative efficacy of these two procedures in SCH. Most existing studies focus on individual therapies or herbal formulations, leaving a critical research gap regarding comparative effectiveness within a structured equivalence trial design.

The present study is therefore conceptualized to address this gap by systematically comparing the efficacy of Vamana karma and Virechana karma in the management of Subclinical Hypothyroidism. The inclusion of standardized preparatory procedures such as *Deepana-Pachana*, *Rookshana*, and *Snehapana*—including the innovative use of *Guggulu Tiktaka Ghrita*—further strengthens the scientific rigor and therapeutic coherence of the protocol.[42,43]

By integrating objective biochemical parameters (thyroid profile) with anthropometric outcomes (BMI-related weight changes), the study aims to generate clinically relevant evidence aligned with both contemporary biomedical standards and classical Ayurvedic principles.

Interdisciplinary Relevance

This study holds substantial interdisciplinary relevance across endocrinology, cardiology, integrative medicine, public health, and traditional medicine research.

From an endocrinological standpoint, SCH represents a diagnostic and therapeutic dilemma due to uncertain thresholds for treatment initiation and variable clinical outcomes. Comparative evidence on non-pharmacological or integrative interventions may provide valuable adjunctive strategies for early-stage disease management.

Cardiovascular medicine is directly implicated, given the established association between SCH and dyslipidemia, coronary artery disease, and heart failure. Interventions that potentially modulate metabolic parameters may have implications for long-term cardiovascular risk reduction.

In the domain of integrative medicine, the study bridges classical Ayurvedic detoxification concepts with modern clinical trial methodology, including randomized allocation, equivalence design, objective biochemical outcomes, and statistical validation. This methodological integration enhances the credibility and translational potential of traditional therapies.

From a public health perspective, SCH disproportionately affects women of reproductive and middle age and contributes to reduced quality of life and increased healthcare utilization. Exploring cost-effective, culturally acceptable therapeutic modalities may reduce long-term disease burden and dependency on lifelong pharmacotherapy.

Thus, the study not only addresses a clinically relevant endocrine disorder but also contributes to evidence-based validation of traditional therapeutic approaches within a modern scientific framework.

Objectives and Hypothesis

Aim

To assess and compare the efficacy of Vamana karma (therapeutic emesis) and Virechana karma (therapeutic purgation) in the management of Subclinical Hypothyroidism.

Primary Objectives

To evaluate the efficacy of Vamana karma in improving thyroid profile parameters in patients with Subclinical Hypothyroidism.

To evaluate the efficacy of Virechana karma in improving thyroid profile parameters in patients with Subclinical Hypothyroidism.

To compare the efficacy of Vamana and Virechana karma in correcting serum TSH and related thyroid profile parameters.

Secondary Objectives

To assess and compare changes in body weight with respect to BMI following intervention.

To evaluate overall improvement in general well-being of patients with SCH.

Research Question: Is Virechana karma as efficacious as Vamana karma in improving thyroid profile parameters in patients with Subclinical Hypothyroidism?

Hypotheses

Null Hypothesis (H_0): Virechana karma is not as efficacious as Vamana karma in the management of Subclinical Hypothyroidism.

Alternative Hypothesis (H_1): Virechana karma is as efficacious as Vamana karma in the management of Subclinical Hypothyroidism.

By adopting a randomized, reference-standard, controlled, single-blind equivalence design, this study seeks to generate robust comparative evidence that may refine therapeutic decision-making in Subclinical Hypothyroidism within an integrative medical paradigm.

2. Materials and Methods

2.1 Study Design

This study is designed as a randomized, reference-standard controlled, assessor-blinded equivalence clinical trial . The primary objective is to compare the effects of *Vamana* (therapeutic emesis) and *Virechana* (therapeutic purgation) on biochemical thyroid function parameters in patients with subclinical hypothyroidism (SCH).

The study will be conducted in two phases:

Phase I: Pilot study (n = 30; 15 participants per group) to estimate variance and calculate the final sample size.

Phase II: Main equivalence trial based on pilot-derived sample size calculation.

Randomization will be performed in a 1:1 ratio using computer-generated allocation sequences (SPSS software). Outcome assessment will be performed by a blinded assessor.

2.2 Study Area / Setting

The study will be conducted at:

- Department of Panchakarma, Mahatma Gandhi Ayurveda College Hospital and Research Centre (MGACH&RC), Wardha, Maharashtra, India &
- Government Ayurveda college, Vazirabad, Nanded, Nanded-Waghala, Maharashtra 431601.

All laboratory investigations, including thyroid function testing, will be performed in a certified

clinical laboratory following standardized operating procedures.

2.3 Study Population

Participants diagnosed with subclinical hypothyroidism based on biochemical criteria will be recruited from outpatient and inpatient departments.

SCH is defined as:

Serum TSH: 4.5–14.9 mIU/L

FT4 within reference range

Eligible participants will be adults aged 20–50 years of either gender.

2.4 Inclusion Criteria

- Participants meeting all of the following criteria will be included:
- Written informed consent
- Age between 20–50 years
- Serum TSH 4.5–14.9 mIU/L with normal FT4
- Body mass index (BMI) between 18.5–39.9 kg/m²
- Clinically fit for *Vamana* and *Virechana* procedures
- *Madhyam Kostha* (Moderate digestive) and *Madhyam Agnibala* (metabolic status) (as per protocol-defined criteria)

2.5 Exclusion Criteria

- Participants will be excluded if they have:
- Overt hypothyroidism
- Thyroid carcinoma, nodular goiter, thyroiditis, or thyrotoxicosis
- Post-thyroidectomy or post-radioiodine therapy status
- Hypothyroidism during pregnancy or lactation
- Severe systemic illness or contraindications to study procedures
- Chronic obstructive pulmonary disease
- Known autoimmune thyroid disease requiring immediate pharmacotherapy

2.6 Sample Size and Sampling Technique

Method of Randomization, Allocation, and Intervention

This study is designed as a **randomized, reference-standard, controlled, single-blind (assessor-blinded), equivalence clinical trial**, as illustrated in Figure 1 of the study protocol. The methodological framework ensures methodological rigor, minimizes bias, and enhances the internal validity of the trial.

Randomization: A **simple randomization technique** will be employed to allocate participants into two groups in a **1:1 ratio**. Randomization will be performed using Statistical Package for the Social Sciences (SPSS) software to generate a random allocation sequence.

Eligible participants who provide written informed consent and complete baseline assessments will be randomly assigned to either:

Group A (Control Group): Vamana Karma (Therapeutic Emesis)

Group B (Intervention Group): Virechana Karma (Therapeutic Purgation)

Simple randomization ensures that each participant has an equal probability of being assigned to either group, thereby reducing selection bias and improving comparability between groups.

Allocation

Participants will be allocated according to the computer-generated randomization list. The study follows a **single-blind design**, wherein the outcome assessor will remain blinded to the group allocation to minimize assessment bias.

Group A participants will receive **Vamana karma** as the reference standard procedure. Group B participants will receive **Virechana karma** as the intervention procedure.

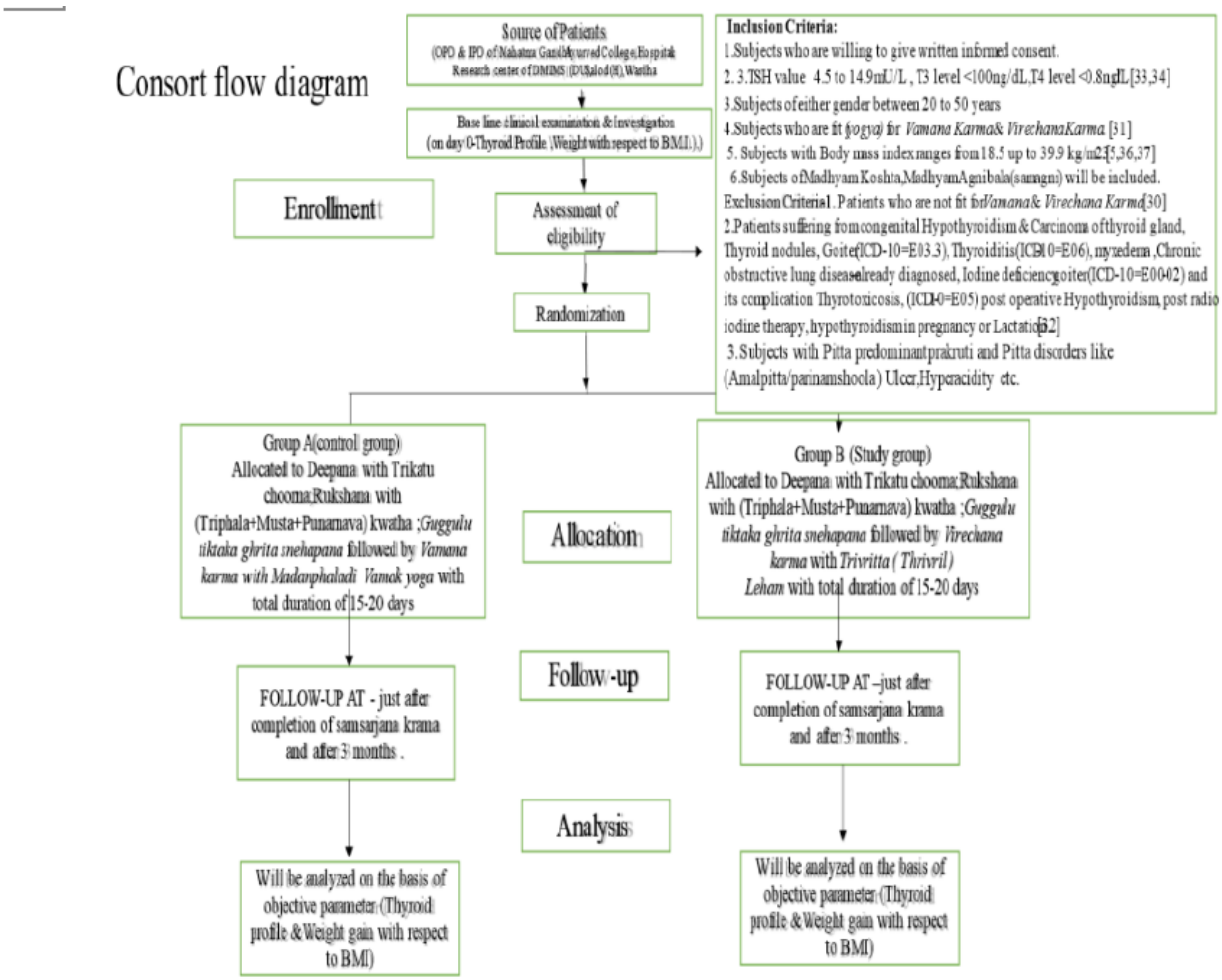
The detailed intervention protocol, including preparatory measures, main procedures, and post-procedure care (Samsarjana Krama), is described in Table 1 of the study protocol.

CONSORT FLOW DIAGRAM:

Study will be conducted in two phases

Phase I - Pilot study- Pilot study will be carried out for the purpose of calculation of sample size.

Phase II - Conduction of detailed study.



Sample Size

The sample size for the present study will be calculated after completion of the pilot study, as

per the protocol described in the uploaded document. Since the study is designed as a **randomized, reference-standard, controlled, single-blind equivalence clinical trial**, the sample size will be determined using the standard formula for equivalence trials.[51]
The general formula applied is:

$$N = 2 \times \left(\frac{Z_{1-\alpha/2} + Z_{1-\beta}}{\delta_0} \right)^2 \times S^2$$

Where:
N = Required sample size in each group
$Z_{1-\alpha/2}$ = Standard normal deviate corresponding to the selected significance level (α)
$Z_{1-\beta}$ = Standard normal deviate corresponding to desired statistical power (1–β)
S^2 = Pooled standard deviation of both comparison groups
δ_0 = Clinically acceptable equivalence margin
The pooled standard deviation (S^2) and clinically acceptable margin (δ_0) will be derived from the results of the pilot study.

Pilot Study

A pilot study will initially be conducted with:
Group A (Vamana Karma): 15 participants
Group B (Virechana Karma): 15 participants
The data obtained from this pilot phase will be used to compute variance estimates and determine the final required sample size for the detailed equivalence trial.

Sampling Technique

The study will employ a **probability-based sampling approach** combined with **random allocation**.

1. Participant Recruitment

Participants will be recruited from the Outpatient Department (OPD) and Inpatient Department (IPD) of the Department of Panchakarma at Mahatma Gandhi Ayurveda College Hospital and Research Centre (MGACH&RC), Wardha, Maharashtra.
Eligible participants will be screened according to predefined **inclusion and exclusion criteria**, including:

- Diagnosed Subclinical Hypothyroidism (TSH 4.5–14.9 mIU/L with normal T3 and T4 levels)
- Age between 20–50 years
- BMI between 18.5–39.9 kg/m²
- Suitability for Vamana and Virechana procedures

Criteria For Discontinuing or Modifying Allocated Interventions:
• Patients willing to quit in between are allowed to quit and will be replaced.
•If the patient develops an acute illness during the trial will be withdrawn.
•Withdrawn patients will be replaced.
This process reflects a **consecutive sampling technique**, where all eligible and consenting

patients presenting during the study period will be considered for enrollment.

2. Randomization and Allocation

After enrollment and baseline assessment, participants will be randomly allocated into two groups in a **1:1 ratio** using **simple randomization** generated through SPSS software.

Group A (Control Group): Vamana Karma

Group B (Intervention Group): Virechana Karma

Randomization ensures:

Equal probability of allocation

Reduction of selection bias

Comparability between groups

The study follows a **single-blind (assessor-blinded) design**, where the outcome assessor will be blinded to group allocation to minimize assessment bias.

Intervention Protocol

Both groups will undergo standard preparatory procedures prior to the main Panchakarma intervention to ensure uniformity and therapeutic adequacy. These include:

1. Deepana–Pachana and Rookshana

Trikatu Choorna

Rukshana Kwatha (Triphala + Musta + Punarnava Choorna)

These formulations are administered to enhance digestive fire (*Agnideepana*), correct metabolic impairment (*Agnimandya*), and prepare the body for Shodhana therapy.

2. Snehapana (Internal Oleation)

Guggulu Tiktaka Ghrita

Administered in increasing doses until attainment of *Samyak Snigdha Lakshanas* (proper oleation signs).

3. Main Procedures

Group A:

Vamana Karma using *Madanphala Pippali Choorna*, along with honey and *Saindhava* (rock salt), as per classical guidelines.

Group B:

Virechana Karma using *Thrivrill Avaleha (Trivritta Leham)* in appropriate dosage based on *Koshta* and *Agni* assessment.

4. Post-Procedural Care

Samsarjana Krama (graduated dietary regimen) will be followed in both groups according to classical guidelines and patient-specific requirements.

Procurement and Quality Control of Study Drugs

All formulations used in this study—including **Trikatu Choorna, Rukshana Kwatha (Triphala, Musta, Punarnava), Guggulu Tiktaka Ghrita, Madanphala Pippali Choorna, Thrivrill Avaleha (Trivritta), Honey, Saindhava, and Dhoomavarti**—will be procured from an authentic and certified pharmacy.

The raw materials for preparation will be obtained from **Manas Ayurved, Nagpur**.

To ensure standardization and quality assurance:

Botanical identification of plant materials will be performed by the institute's staff botanist.

All raw materials will be **GMP-certified** in accordance with Food and Pharmaceutical regulatory norms.

Physico-chemical characterization will be conducted to assess purity and quality parameters.

High-Performance Thin Layer Chromatography (HPTLC) analysis will be carried out at an authorized Pharmacognosy Department to ensure authenticity, consistency, and reproducibility of the formulations.

The study employs a rigorously structured randomization and allocation process, standardized intervention protocol, and validated quality control measures to ensure scientific robustness, therapeutic integrity, and reproducibility of results within an equivalence clinical trial framework.

2.7 Intervention / Study Procedure

Both groups will undergo standardized preparatory procedures:

Deepana–Pachana (digestive stimulation)

Snehapana with *Guggulu Tiktaka Ghrita* in escalating doses

Sarvanga Abhyanga (oil massage)

Bashpa Swedana (steam therapy)

Group A: *Vamana*

- Therapeutic emesis using a Madanaphala-based formulation.

Group B: *Virechana*

- Therapeutic purgation using *Trivritta Leha* (50–70 g adjusted per individual assessment).
- Both groups will undergo **Samsarjana Krama** (post-procedure dietary regimen).
- Laboratory Assessment
- Venous blood samples will be collected in the morning (fasting state) for:
- Serum TSH
- Serum FT4

Assessments will be performed at:

- Baseline
- Post-intervention (after completion of post-therapy regimen)
- 3-month follow-up

2.8 Outcome Measures

Primary Outcomes

- Change in serum TSH concentration
- Change in serum FT4 concentration

Secondary Outcomes

- Change in body weight and BMI
- Clinical well-being assessment
- Thyroid function tests will serve as objective bioanalytical endpoints.

2.9 Statistical Analysis

Statistical analysis will be performed using SPSS (version 20.0) .

Data will be analyzed using equivalence trial statistical methodology.

Descriptive statistics: mean ± standard deviation
Within-group comparisons: paired t-test or equivalent non-parametric test
Between-group comparisons: independent t-test
Equivalence margin predefined
Significance level set at $p < 0.05$
Intention-to-treat principles will be applied where appropriate.

2.10 Ethical Approval

The study will be conducted in accordance with:
ICMR guidelines (2017)
Declaration of Helsinki principles
Institutional Ethics Committee approval has been obtained (Ref No. MGACHRC/IEC/June 2022/509 dated 18.06.2022), and the trial is registered with the Clinical Trials Registry of India (CTRI/2022/12/047833) .
Written informed consent will be obtained from all participants prior to enrollment.

3. Results

As this manuscript presents a **study protocol**, no outcome data are currently available. The trial has been designed as a randomized, reference-standard, controlled, single-blind equivalence clinical study to evaluate and compare the efficacy of Vamana Karma and Virechana Karma in the management of Subclinical Hypothyroidism (SCH).

The primary outcomes proposed for assessment include:

- Changes in thyroid profile parameters (Serum TSH, T3, and T4 levels)
- Changes in body weight with respect to Body Mass Index (BMI)

Secondary outcomes include improvement in general well-being of patients with SCH.

- Data will be collected at three time points:
- Baseline (prior to intervention)
- Immediately after completion of Samsarjana Krama

At 3-month follow-up

Statistical analysis will be conducted using appropriate methods for equivalence trials after completion of the study period. The final results will determine whether Virechana Karma is therapeutically equivalent to Vamana Karma in improving thyroid profile parameters and associated clinical indicators.

Trial Status

Recruitment of study participants commenced in February 2023. The trial is currently ongoing. Final data analysis will be performed after completion of enrollment, intervention, and follow-up. The findings will be disseminated through national and international peer-reviewed journals upon completion of the study.

4. Discussion

Interpretation of Findings

This study protocol has been designed to evaluate and compare the efficacy of Vamana Karma

and Virechana Karma in the management of Subclinical Hypothyroidism (SCH) within a randomized, controlled, equivalence trial framework. As the trial is ongoing, definitive findings are not yet available. However, the conceptual interpretation underlying this protocol is grounded in both contemporary endocrinology and classical Ayurvedic principles.

SCH represents an early stage of thyroid dysfunction characterized by elevated TSH with normal peripheral thyroid hormone levels. Although frequently asymptomatic, it may progress to overt hypothyroidism and is associated with metabolic and cardiovascular risks.[6,8,9] Current management strategies remain controversial, particularly in patients with mildly elevated TSH levels. The present protocol is based on the hypothesis that Shodhana therapies—specifically Vamana and Virechana—may correct underlying metabolic dysfunction (*Agnimandya*) and prevent disease progression.

From an Ayurvedic standpoint, SCH corresponds to *Jatharagnimandya* and *Dhatwagnimandya* with predominance of *Kapha* and *Vata* doshas in a state of *Bahudoshavastha*. The asymptomatic or minimally symptomatic stage aligns with *Avyakta Avastha*, where pathology exists but has not yet fully manifested. Therefore, early intervention through *Agnideepana* and *Srotoshodhana* is considered rational and potentially preventive. The study is structured to evaluate whether these classical detoxification therapies can restore metabolic balance as reflected in objective thyroid parameters.

Comparison with Previous Studies

Previous biomedical studies have demonstrated that SCH is associated with cardiovascular morbidity, dyslipidemia, and impaired quality of life. However, evidence regarding the benefits of levothyroxine therapy in mild SCH remains inconsistent, particularly in younger and asymptomatic individuals.[11,12] Some meta-analyses suggest limited symptomatic or cardiovascular benefit in borderline cases, contributing to ongoing clinical uncertainty.

Within the Ayurvedic literature, thyroid disorders are described under *Galaganda*, and Shodhana therapies are indicated in conditions involving Kapha predominance and metabolic impairment.[34-36] Prior Ayurvedic clinical studies have explored the use of herbal formulations such as Triphaladya Guggulu and Punarnavadi Kashaya in hypothyroid conditions, demonstrating symptomatic and biochemical improvement.[26] However, comparative clinical trials evaluating classical Panchakarma procedures—particularly head-to-head comparisons between Vamana and Virechana—are scarce.

The present protocol addresses this gap by employing a randomized equivalence design to systematically compare two classical detoxification procedures. Furthermore, the incorporation of standardized preparatory measures and quality-controlled formulations enhances methodological rigor compared to earlier observational or single-arm studies.

Possible Mechanisms :

The therapeutic rationale of this study is based on the principle that SCH reflects impaired metabolic fire (*Agni*) and accumulation of vitiated doshas affecting systemic channels (*Srotas*).

Deepana–Pachana and Rookshana: These preparatory interventions aim to enhance digestive and tissue metabolism, reducing *Ama* (metabolic toxins) and correcting *Agnimandya*. The use of Triphala, Musta, and Punarnava is selected considering Kapha and Meda involvement in the pathogenesis of SCH.

Snehapana with Guggulu Tiktaka Ghrita: Guggulu has documented anti-inflammatory and cardioprotective properties in pharmacological studies. Its classical indication in *Shotha*,

Hridroga, and *Gandamala* supports its selection. It may modulate inflammatory pathways and metabolic processes, potentially influencing thyroid regulation.

Vamana Karma: Traditionally indicated in Kapha-dominant disorders, Vamana eliminates accumulated doshas from the upper gastrointestinal tract. It may influence neuroendocrine pathways through gut–brain–thyroid axis interactions.

Virechana Karma: As a controlled purgation therapy, Virechana facilitates elimination of vitiated Pitta and Kapha through the lower gastrointestinal tract. It may improve metabolic homeostasis, hepatic function, and systemic detoxification processes.

From a biomedical perspective, these interventions may modulate inflammatory mediators, improve lipid metabolism, influence autonomic regulation, and enhance metabolic signaling pathways, thereby potentially contributing to normalization of TSH levels.

Strengths and Limitations

Strengths

Randomized, reference-standard, controlled equivalence design
Assessor blinding to minimize measurement bias
Use of objective biochemical parameters (TSH, T3, T4) as primary outcomes
Integration of classical Ayurvedic rationale with modern clinical trial methodology
Standardized and GMP-certified formulations with quality control measures
Inclusion of follow-up assessment to evaluate sustainability of outcomes

Limitations

Single-center study design, which may limit generalizability
Results are pending as the trial is ongoing
Follow-up duration limited to three months
Lack of placebo or conventional pharmacological comparison arm
Complete participant blinding is not feasible due to the procedural nature of Panchakarma

Conclusion:

The present protocol proposes a scientifically structured comparison of Vamana Karma and Virechana Karma in Subclinical Hypothyroidism based on the concepts of *Agnideepana* and *Shodhana*. By addressing both metabolic dysfunction and systemic imbalance at an early stage, this study aims to generate evidence that may broaden integrative therapeutic options for SCH. The final outcomes of the ongoing trial will determine the clinical applicability and equivalence of these two Panchakarma procedures in endocrine practice.

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