Evaluation of Comparative Efficacy of Levothyroxine versus Kshar Basti and Kanchanar Guggul in the Treatment of Hypothyroidism: A Study Protocol for Randomized Control Trial

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Abstract

Background: The thyroid gland is an endocrine gland that has an impact on the body's general metabolism. Thus, the secretions of the thyroid gland can modify the overall metabolism of the entire body. The prevalence of hypothyroidism is increasing quickly, with rates of 2- 5% in affluent countries and 11% in India. Individuals diagnosed with hypothyroidism need to take medication for the rest of their lives, resulting in a significant stress. Therefore, conducting a study in this area is imperative.

Objective: To assess the effectiveness of the therapeutic enema (Kshar Basti) and oral Kanchnar Guggul in the treatment of hypothyroidism.

Methods: The study group (n=45) will receive a therapeutic enema (Kshar Basti) followed by oral Ayurvedic drugs for 180 days. The control group (n=45) will be given Levothyroxine tablets at a dosage of 1.6 µg/kg/day for the same duration. The objective is to examine the alterations in TSH levels before and after the treatment.

Results: Any deviation of the serum Thyroid Stimulating Hormone (TSH) by more than 20% from the initial values, while keeping Triiodothyronine
(T3), and Thyroxine (T4) levels within the normal range, will be deemed statistically significant. Consequently, we anticipate a statistically significant variation in serum TSH levels between the therapeutic enema and Kanchanar Guggul treatments. Presently, the drug preparation operations are in progress. We anticipate commencing patient recruitment in June 2024, conducting data analysis in June 2025, and obtaining results by the conclusion of the year 2025.

Conclusions: This study will evaluate the efficacy of the therapeutic enema, specifically Kshar Basti, in treating hypothyroidism. Furthermore, more research can determine the efficacy of a therapeutic enema (Kshar Basti) in treating overt hypothyroidism and hypothyroidism during pregnancy. Clinical Trial: Trial Registration: CTRI/2023/05/052389 [Registered on: 09/05/2023] Trial Registered Prospectively version 2.

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We expect to start enrolling patients in June 2024, do data analysis in December 2025, and acquire results by early 2026, marking the end of this trial.
Conclusions: This study will evaluate the efficacy of the therapeutic enema, specifically Kshar Basti, in treating hypothyroidism. Furthermore, more research can determine the efficacy of a therapeutic enema (Kshar Basti) in treating overt hypothyroidism and hypothyroidism during pregnancy.

Trial Registration: CTRI/2023/05/052389 [Registered on: 09/05/2023] Trial Registered Prospectively version 2.
Keywords: Ayurveda; Complementary and Alternative Medicine; hypothyroidism; Levothyroxine; Rectal enema; Massage therapy; Sudation

Introduction

Thyroid hormones have various impacts on different biological systems. They play a crucial role in regulating many physiological processes, such as the vascular system, heart function, brain function (including cognition and mood), skeletal muscle, and bone health. Hypothyroidism refers to the inadequate production of thyroid gland secretions.

Hypothyroidism is primarily characterized by subclinical hypothyroidism (SCH), where levels of thyroid-stimulating hormone (TSH) are elevated, but both free thyroxine (T_4) and triiodothyronine (T_3) levels remain within the normal range [1]. Overt hypothyroidism is the second kind of

hypothyroidism, characterized by an increase in TSH, a drop in T_4 and T_3 levels, and the presence of clinical symptoms indicating hypothyroidism.

As per recommendations from endocrine societies, SCH is frequently managed with L-thyroxine. This approach perhaps led to L-thyroxine becoming the most often prescribed medication in the United States starting in 2014, with over 15% of Americans aged 61 and older using it. A recent extensive study conducted on older adults, known as the TRUST (Thyroid Hormone Replacement for Untreated Older Adults with Subclinical Hypothyroidism Trial), along with a subsequent thorough analysis of randomized controlled trials, found no evidence of any advantages of L-thyroxine in terms of symptom relief or improvement in quality of life for patients with SCH [2]. Nevertheless, L-thyroxine is typically recommended indefinitely for SCH, which can be stressful for patients [3].

SCH is a burgeoning lifestyle-related ailment in India. In prosperous countries, the prevalence rate of hypothyroidism ranges from 2 to 5 percent. However, in India, the prevalence rate is 11 percent [4].

The prevalence rate of hypothyroidism increases with advanced age [5]. The American Thyroid Association guidelines advise the use of L-thyroxine in individuals with SCH and a TSH level of 10 mIU/L or higher. The supposition of SCH leading to overt hypothyroidism (OH) is the basis of this statement [6].

There are two primary issues associated with L-thyroxine therapy, one of which is the uncertainty around the role of L-thyroxine in subclinical hypothyroidism (SCH). There are conflicting observations regarding it, and the patient must take L-thyroxine for the rest of their lives, which is distressing. Hence, there is an urgent requirement for Ayurvedic therapies in SCH.

Ayurveda is practiced in India, Nepal, and Sri Lanka, and is increasingly being adopted in Western countries. Western allopathic medicine has demonstrated efficacy in managing acute medical emergencies, while Ayurveda may effectively handle chronic conditions that pose challenges for Western medical treatment. Individuals diagnosed with hypothyroidism frequently pursue Ayurvedic remedies [7].

Ayurveda recognizes a limited number of disorders that might be associated with hypothyroidism, and by applying Ayurvedic principles, it is possible to effectively manage this illness. Previous research [8] has examined the effectiveness of Ayurvedic treatment for hypothyroidism in multiple studies [9,10,11]. Nevertheless, these studies are subject to notable constraints, such as the lack of randomization, the absence of consistent therapy in the control group, a poor sample size, and insufficient follow-up time. We have chosen the following research to revise our protocol to overcome their limitations.

A recent study [10] demonstrated that administering Basti for a duration of 30 days, together with oral intake of one gram of Kanchanar Guggul twice a day with tepid water, and Vardhaman Pippali for 12 weeks, yielded better results compared to using only Kanchanar Guggul and Vardhaman Pippali in the same dosage for 12 weeks. However, the study conducted for only 12 weeks is inadequate to induce alterations in TSH concentration. Thus, we selected Kanchanar Guggul as the designated medication.

A study [12] indicated that a therapeutic decoction enema (Kshar Basti) was effective in treating hypothyroidism. A 10-day therapy regimen consisting of oral medications and therapeutic enemas using a decoction called Kshar Basti resulted in significant improvement in the symptoms of hypothyroidism. After two months of follow-up, the level of serum TSH decreased to 5.76 mIU/L, while T_3 and T_4 remained within the normal range. However, it is important to note that this study is limited to a single example.

Objectives

Research question.

Can Ayurvedic treatments involving Kshar Basti (a therapeutic enema with herbal decoction) and

oral administration of Kanchanar Guggul tablet effectively treat SCH?

Hypothesis

In subclinical hypothyroidism, the administration of Ayurvedic interventions, specifically Kshar Basti (decoction enema) followed by oral Kanchanar Guggul, has the potential to decrease elevated TSH levels while maintaining normal T_3 and T_4 levels.

Primary Objective

The main goal is to ascertain whether Ayurvedic therapy involves the administration of Kshar Basti, which is a herbal decoction enema, followed by an oral tablet. Kanchanar Guggul is efficacious in treating SCH.

Secondary objective

Our secondary goal is to evaluate the appropriateness of Basti Karma (rectal enema therapy) and determine the dropout rate of the Basti course.

Methods

To assess and compare the effectiveness of the therapeutic decoction enema (Kshar Basti) and Kanchanar Guggul with L-thyroxine in the treatment of hypothyroidism, we will administer the therapeutic enema (Kshar Basti) for 24 days, followed by oral intake of Kanchanar Guggul for 153 days (a total of 180 days) in the study group. In the control group, tab. L-thyroxine will be taken for 180 days. The results will then be evaluated.

Ethical considerations

This study plan was presented to the Institutional Ethical Committee (IEC) of Mahatma Gandhi Ayurved College, Hospital, and Research Centre, salod, Wardha, India, and approval from the IEC has been obtained. (Ref. MGACHRC/IEC/May-2022/479, dated May 23, 2022)

The subjects of SCH will be informed regarding the ayurvedic procedures and the medications, and their written consent will be obtained on an informed consent form that is prepared in English and Marathi.

Periodically, participants will be required to provide their consent for panchakarma treatments and the collection of blood samples.

Study setting:

This is a single-blind, randomized controlled clinical trial (RCT) that aims to determine the superiority of one treatment over another(Figure 1). The study consists of two arms and follows a prospective design. Participants will be randomly assigned to either arm in a 1:1 ratio.

The study will be carried out in the Panchakarma dept. of the hospital affiliated with Mahatma Gandhi Ayurvedic College, hospital, and Research Center, Salod, Dist. – Wardha-442004, Maharashtra, India. This study will be conducted following SPIRIT standards for RCTs (Table 1).

Table 1. SPIRIT flow chart.

	Enrollment	**Allocation**	**Post allocation**				**Close out**
TIMEPOINT			0^{th} day	3^{rd} day	24^{th} day	180^{th} day	181^{st} day
ENROLLMENT							
Eligibility screen	X						
Informed consent	X						
Allocation		X					
INTERVENTION							
Deepan -Pachan							
Ksharbasti							

Tab.Kanchnar Guggul Levothyroxine Tablets							
ASSESSMENT Baseline post-intervention							
			x				
							X

Diagnostic criteria

The diagnosis of SCH will be made as per International Classification of Diseases (ICD) -10 criteria (SCH) TSH> 4.50 µIU/mL, fT4 – 0.8 -1.8 ng/dL, fT3 – 1.4 -4.4 Pg/ML. [13]. (Textbox 1.)

Grouping

parallel design.
Group A – the control group – 45 subjects.
Group B – the study group – 45 subjects.

Interventions

In this randomized clinical trial, Group A, referred to as the control group, will be administered conventional treatment, while Group B, referred to as the study group, will be administered Ayurvedic treatment (Textbox.2,Figure 1.)

Randomization

We will apply random allocation to recruit the participants in the study. Computer-generated random numbers will be used.

Blinding

The allocation will be researcher-blind. A third person, such as a nurse or Panchakarma therapist, will help to allocate the subject using computer-generated random numbers. Since this study is researcher-blind, a PhD guide will allocate and assign the participants.

Screening investigations

Serum TSH will be measured before and after the study. On the 181st day, serum TSH, T_3, and T_4 will be measured. The above findings will be compared to the baseline findings.

Criteria of the assessment/outcome variable

A variation of more than 20% of the baseline value of serum TSH with normal values of T_3 and T_4 will be considered to determine the efficacy of the intervention. Therefore, decreasing serum TSH with no change in T_3 and T_4 means, Kshar Basti with Kanchnar Guggul is efficacious in SCH.

Interventions for the Study Group

1) Deepan- Pachan-

Shivakshar Pachak Churna is an Ayurvedic medication that should be taken orally, with a dosage of 1 gram, twice a day, for 3 days. (Table.2) Before commencing Basti therapy, it will enhance the appetite, a crucial factor. The preparation will be conducted in the pharmacy that is connected to our institute.

Table 2. Shivakshar Pachak Churna- contents

Ayurvedic name	Latin name/English name
Sunthi	Zinziber officinale
Marich	Piper nigrum
Pippali	Piper longum
Ajmoda	Trachyspermun roxburghianum
Jeeraka	Cuminum cyminum
Krishnajeerak	Nigella sativa
Hingu	Ferula asa foretida
Haritaki	Terminalia chebula
Saindhav	Rock salt
Sajjikshar	Carbonate of soda

2) Kanchanar Guggul [10]

It will be prepared in the pharmacy attached to our hospital. It will be designed per the SOP mentioned in the pharmacy attached to the hospital. The contents are provided in the table (Table 3).

Table 3. Kanchnar Guggul- contents

Ayurvedic name	Latin name
Kanchanar	Bauhinia variegate linn
Amalaki	Embellica officinalis
Haritaki	Terminalia chebula
Bhibtak	Terminalia belerica
Pippali	Piper longum
Varuna	Crataeva reiligios
Dalchini	Cinnamonum cassia
Ela	Elletaria cardamomum
Tejpatra	Cinnamomum Tamal
Guggul	Commiphora mukul

3) Kshar Basti

The procedure of Kshar Basti:

a) Pre-operative:

Kshar Basti [12] is a therapeutic decoction enema [14]. Therefore, we will follow the same operative procedures that apply to Niruha Basti. The Yoga Basti method (Figure 2) will administer Niruh Basti and Anuvasan Basti (therapeutic unctuous enemas) on alternate days, except the last day. For three days, we will administer Deepan-Pachan, which enhances metabolic fire. Kshar Basti's decoction will be prepared per the Standard Operating Procedures (SOPs) followed in the hospital. Table 4 lists Kshar Basti's contents (Table 4). For the Anuvasan Basti, we will use plain sesame oil. We will call the subjects to the hospital early for the Kshar Basti during the day (before 3:00 PM). Sesame oil massage and hot fomentation will be performed on the whole body. The fomentation will be conducted as per the SOPs of the hospital as mentioned by the National Accreditation Board for

Hospitals (NABH).

Table 4. Kshar Basti - contents

Content	Quantity
Jaggery (Guda)	100 gm
Tamarind pulp (Amlika)	100 gm
Rock salt (Saindhav)	10 gm
Cow's urine (Gomutra)	400 ml
Paste of Anthem Sova (Shatavha Kalka)	10 gm
Total	**500 ml**

b) Operative:

The raw medicines will be collected, prepared, and made lukewarm by indirect heating. Materials will be taken into an enema can. The subject will be asked to lie over the table in the left lateral position. The nozzle of the enema can be slowly inserted into the anal canal after applying oil to it. The nozzle will be slowly inserted till it reaches the rectum, and now the decoctions will enter the rectum. Soon after the administration of Kshar Basti, the subject will be allowed to defecate.

c) Post-operative:
The subject will be asked to follow a dietary regimen like *Yusha* (a soup of vegetables or pulses) and rice and drink hot water during the Kshar Basti course.
Course duration: Basti will be administered daily for eight days; after that, the subject must follow the regimen for 16 days. The total duration of the course will be 27 days (including Deepan-Pachan - 3 days), and after this course, Kanchanar Guggul will be administered for 153 days.
Duration of therapy: 180 days
Follow-up period: 180 days
Both groups of patients are restricted from taking or consuming any medications, devices, or non-pharmacological treatments that have an impact on hypothyroidism.

Sample Size Calculations.

We used the following formula for the determination of sample size [15]

$$N = 2 \times \left(\frac{z_{1-\alpha} + z_{1-B}}{1-\delta_0} \right)^2$$

N = 40

Thus, there will be 45 participants in each group (5 added to minimize the error), and our study's sample size will be 90 (n = 90).
We also noted the sample size utilized in past studies conducted on hypothyroidism at this institute.

Thus, a sample size of 90 would be both practical and adequate.

(N=size per group; $z_{1-\alpha}$= the standard normal deviate for one group; $z_{1-\beta}$= the standard normal deviate for the other group, δ_0= a clinically acceptable margin.)

Data collecting methods.

The researcher will gather and archive the data. The data will be collected using appropriate software, such as Epi-Info. We will examine the data after the trial concludes. Replicates will be discarded. We will choose a conventional laboratory to quantify serum TSH.

Data Confidentiality

Only the PhD guide will have access to the acquired data, which includes biological samples from the individuals. However, upon completion of the study, any researcher may request access to the data for a systematic review and meta-analysis.

Audit

We will conduct the audit six months after the trial begins, under the supervision of a PhD mentor. Furthermore, we will closely observe and track any negative reactions caused by the drugs or treatments used in our operations, as well as ensure strict adherence to the established protocol.

We will educate the participants about the favorable attributes of Kshar Basti (the therapeutic enema), to ensure their compliance with the treatment regimen and adherence to the established procedures. We will closely observe the reduction in participants from this experiment and the factors contributing to this reduction.

Statistical Analysis

After summarizing the data, we will use the Kolmogorov-Smirnov test to decide if the data is following a normal distribution. If normally distributed, the student's T-test will be used; otherwise, the Z test' will be applied. We will use IBM SPSS (Version 26) for statistical analysis. We will set the P value to less than 0.05 for statistical significance.

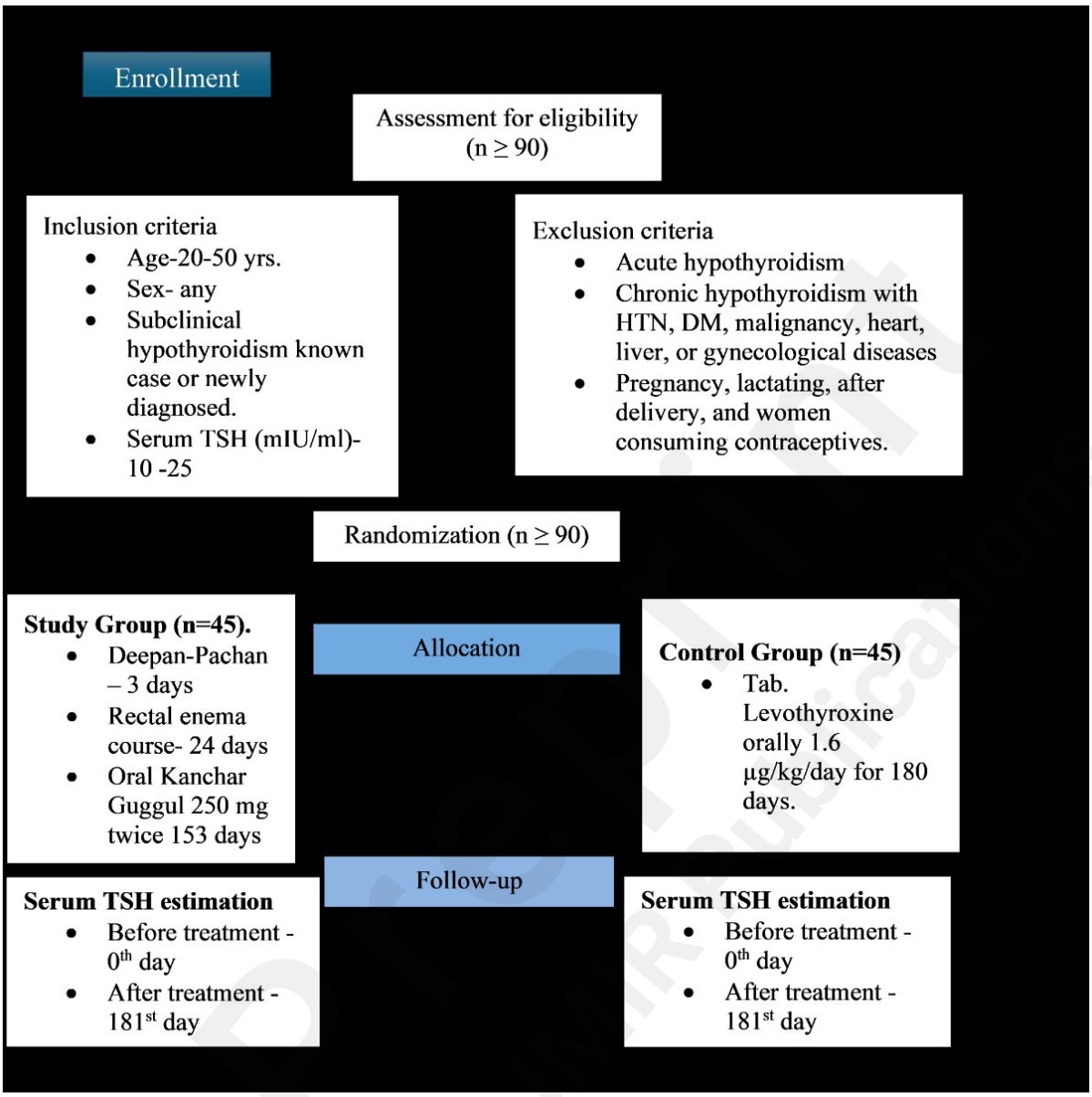
Results

We will examine the following factors in the demographics: - Age - Gender - Location - Smoking behavior - Alcohol consumption - And the type of salt used to achieve the secondary purpose of this study, we will examine the rate at which students drop out of the Kshar Basti course, as well as any occurrences of difficulties associated with the Kshar Basti course.
We will only recruit subjects for this study once, we have accepted or published the manuscript. We will finish the drug preparation and acquisition by June 2024. The projected timeline for the recruitment process is June 2024 to December 2025. We will evaluate the information right away and conclude at the start of 2026.

Evaluation Outcomes

The primary assessment result of our study is the disparity in the TSH, T3, and T4 levels compared to the initial values. We will deem any deviation of 20% or more from the baseline as statistically significant.

Figure 1. Study design.



Textbox 1. Eligibility, exclusion, withdrawal, and Adverse Drug Reaction criteria.

Eligibility criteria

1. Age – 20 – 60..
2. Sex – Any.
3. Known case, or newly diagnosed case of SCH.

Exclusion criteria

1. overt hypothyroidism.
2 SCH associated with Diabetic Mellitus, hypertension, pregnancy, and gynecological disorders.
3. Hashimoto’s thyroiditis.

4.Kshar Basti contra-indications.

Withdrawal criteria:

The participant may be withdrawn from the trial if there is one of the following -

1. Any adverse event and adverse drug reaction occurrence.
2. Voluntary withdrawal by the subject.
3. Violation of inclusion and exclusion criteria.
4. There is non-compliance with the treatment regimen (A minimum of 80% Compliance is essential to continue in the study).

Adverse Drug Reaction (ADR)

If an ADR occurs during the trial, the subject will be treated at the institute-attached hospital, and the investigators will cover the costs.

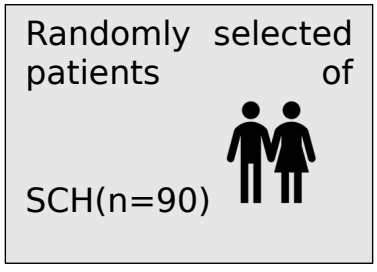
Criteria for discontinuing from the trial.

If the subject breaks the sequence of panchakarma therapy and misses the oral therapy for ≥ 7 days, he/she will not be considered in the trial.

Textbox 2 . Interventions

- For Group A (the trial group), the therapeutic decoction enema (Kshar Basti) with oil massage to the whole body, followed by hot fomentation before the enema, will be administered for eight days. We will use the Course of Eight Therapeutic Enemas (Yoga Basti) method. We will use plain sesame oil for the therapeutic unctuous enema (Anuvasan Basti).
- For Group B (the control group), levothyroxine tablets at a dose of 1.6 µg/kg/day will be administered for 180 days.

Figure 2. Intervention details.



Pre-operative Deepan-pachan-3 days
Shivakshar Pachak Churn 1gm 2 times orally for 3 days.

L-thyroxine
Levothyroxine tablets orally 1.6 µg/kg/day for 180 days.

Operative -Rectal enema course – 8 days
Oil massage and sudation to the whole body followed by a rectal enema. Rectal enema containing sesame oil and Kshar Basti on the following sequence,

D	1	2	3	4	5	6	7	8
E	OE	KB	OE	KB	OE	KB	OE	OE

Post-operative – Dietary regimen – 16 days
certain dietary and behavioral restrictions to be followed.

Kanchnar Guggul
Tab 250 mg twice for 153 days

Analysis

Discussion

The 45 subjects in the control group will receive oral L-thyroxine. On the other hand, the study group, also consisting of 45 participants, will get a treatment involving Kshar Basti and oral Kanchnar Guggul tablets. Both groups will undergo treatment for 180 days, and on day 181, we will assess the levels of TSH, T3, and T4 in the blood. We will compare the changes before and after therapy. We expect that the Ayurvedic intervention, specifically the combination of Kshar Basti and Kanchnar Guggul, will demonstrate statistically significant outcomes compared to the standard treatment. This would establish Ayurvedic intervention as a viable treatment option for Subclinical

hypothyroidism, eliminating the need for lifelong consumption of levothyroxine tablets by the patient.

Hashimoto's thyroiditis typically correlates with hypothyroidism. The thyroid gland produces numerous growth and vasoactive substances. The epithelial cells of the thyroid gland contain the glycoprotein known as Vascular Endothelial Growth Factor (VEGF). It plays a critical role in the elevated levels of thyroid stimulating hormone (TSH) in subclinical hypothyroidism (SCH).

A study compared the administration of Nigella sativa powder at a dosage of 2 grams per day for 8 weeks with the administration of placebos consisting of starches at the same dosage and duration. This randomized clinical trial (RCT) involved 47 human participants diagnosed with Hashimoto's thyroiditis. Nigella sativa treated 23 of them, while starches served as a placebo for the remaining 24. The study determined that Nigella sativa seeds were useful in alleviating Hashimoto's thyroiditis. It also successfully reduced VGEF levels and body weight.

In Ayurveda, Nigella sativa is referred to as 'Krishnajeeraka'. In our study, we will be administering Shivakshar Pachak Churna as 'Deepan-Pachan' for the first three days. Nigella sativa is a constituent of Shivakshar Pachak Churna[16].

In a separate trial, [17] the authors randomly assigned 53 individuals with hypothyroidism to either the treatment group or the control group, administering a placebo to the latter. The ginger group, consisting of 27 participants, was given a 500 mg capsule containing ginger twice a day, whereas the placebo group, consisting of 26 participants, was given starch. This treatment lasted for 30 days. Both groups were administered levothyroxine. The Thyroid Symptoms Rating Questionnaire (ThySRQ) was used to evaluate the results. The initial findings of this trial showed that individuals with primary hypothyroidism who consumed ginger powder daily while receiving appropriate hormone replacement therapy (achieving biochemical euthyroid) experienced a notable decrease in symptoms associated with hypothyroidism. Our study incorporates Zanzibar as a component of the 'Shivaksharpachak Churna'.

Basti therapy is recommended for the treatment of numerous physical and psychological conditions [18]. Immunomodulation was observed following Basti, according to a study that evaluated the metabolic and immunologic response to Basti therapy. One potential mechanism by which it operates is by modulating T cells, immunoglobins, and pro-inflammatory mediators.

A study [17] found that over 50% of people with hypothyroidism have Small Intestinal Bacterial Overgrowth (SIBO). The study found that 54% of hypothyroidism patients tested positive for SIBO using the glucose breath test, compared to 5% in the control group. Diarrhea is a common symptom among hypothyroidism patients, with a positive hydrogen breath test and antibiotic response indicating SIBO. Hypothyroidism can cause less movement in the gastrointestinal tract, leading to long-lasting gastrointestinal problems.

An additional investigation [18] demonstrated that 300 mg of Ashwagandha root extract twice daily for eight weeks produced statistically significant outcomes. The impact of Ashwagandha root extract on the Hypothalamic-Pituitary-Thyroid Axis (HPA) was hypothesized by the authors. Ashwagandha has anti-dopaminergic and anti-inflammatory properties. These characteristics may contribute to the thyroid-modulating effect.

Kshar Basti is a therapeutic mixture containing Tamarindus pulp, which acts as a laxative and helps alleviate gastrointestinal troubles[19]. Jaggery is beneficial for the gut microbiota[20]. It is believed that Shatavha (Anthem sowa) possesses estrogenic characteristics[21]. It affects the blood, bones, and central nervous system. The rock salt contains sodium, potassium, and chloride ions[22]. It causes the solution to become hypertonic. Guggul is derived from the latex of the Guggul plant. Recently, an article revealed the anti-hypothyroidism properties of the Guggul herb[23]. Therefore, the Ayurvedic treatment involving Kshar Basti and Kanchnar Guggul is believed to enhance the immune system and alleviate subclinical hypothyroidism.

The efficacy of Kshar Basti and Kanchanar Guggul in the treatment of hypothyroidism can be

substantiated with dependable evidence in this study, owing to its randomized controlled trial design and moderate sample size of 90. In addition, the duration of the study will be 180 days, which is sufficient to detect fluctuations in TSH and thyroid hormone levels.

Principal Results

The primary findings will establish that the Ayurvedic therapy including Kshar Basti (administration of herbal decoction through enema) followed by oral administration of Tab Kanchanar Guggul is effective in treating hypothyroidism.

Publication plan

We intend to disseminate the results of our study by publishing it as either an original research article or a short communication in a journal that is indexed.

Limitations

Our investigation has some limitations. To begin with, 90 samples is still a moderate amount. To account for this prevalence rate, a minimum of 300 samples would be adequate. The duration of treatment is extended. Consequently, a large dropout rate is possible. Hence, a practical sample size of 90 was selected.

The preventive effect of these Ayurvedic interventions on SCH cannot be determined through our research. To accomplish this, an additional observational study with a minimum one-year follow-up period is required.

Conclusions

Our proposed study will evaluate the effectiveness of Ayurvedic intervention, specifically Kshar Basti and oral Kanchnar Guggul tablets, in managing subclinical hypothyroidism. Additionally, we will assess the appropriateness of the Kshar Basti course. The findings of this study will provide evidence for the use of Ayurvedic treatment as an option for subclinical hypothyroidism.

We suggest doing a further investigation to assess the independent effectiveness of Kshar Basti and Kanchnar Guggul in alleviating overt hypothyroidism. There is a need for a study to assess the effectiveness of these Ayurvedic therapies in treating hypothyroidism during pregnancy.

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Conflicts of Interest

None declared.

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None

Abbreviations

D-day
E-enema
KB- Kshar Basti
L-thyroxine – Levothyroxine

OE-oil enema,
SOP-Standard Operating Procedure
SCH: Subclinical hypothyroidism
TSH-Thyroid Stimulating Hormone.

Author's contributions

SK reviewed the literature, conceptualized the study, presented it to the IEC, Obtained the IEC approval, prepared the manuscript and revision,
SP reviewed the literature, conceptualized the study, guided the presentation to IEC, and helped to prepare the manuscript and revision.

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Supplementary Files

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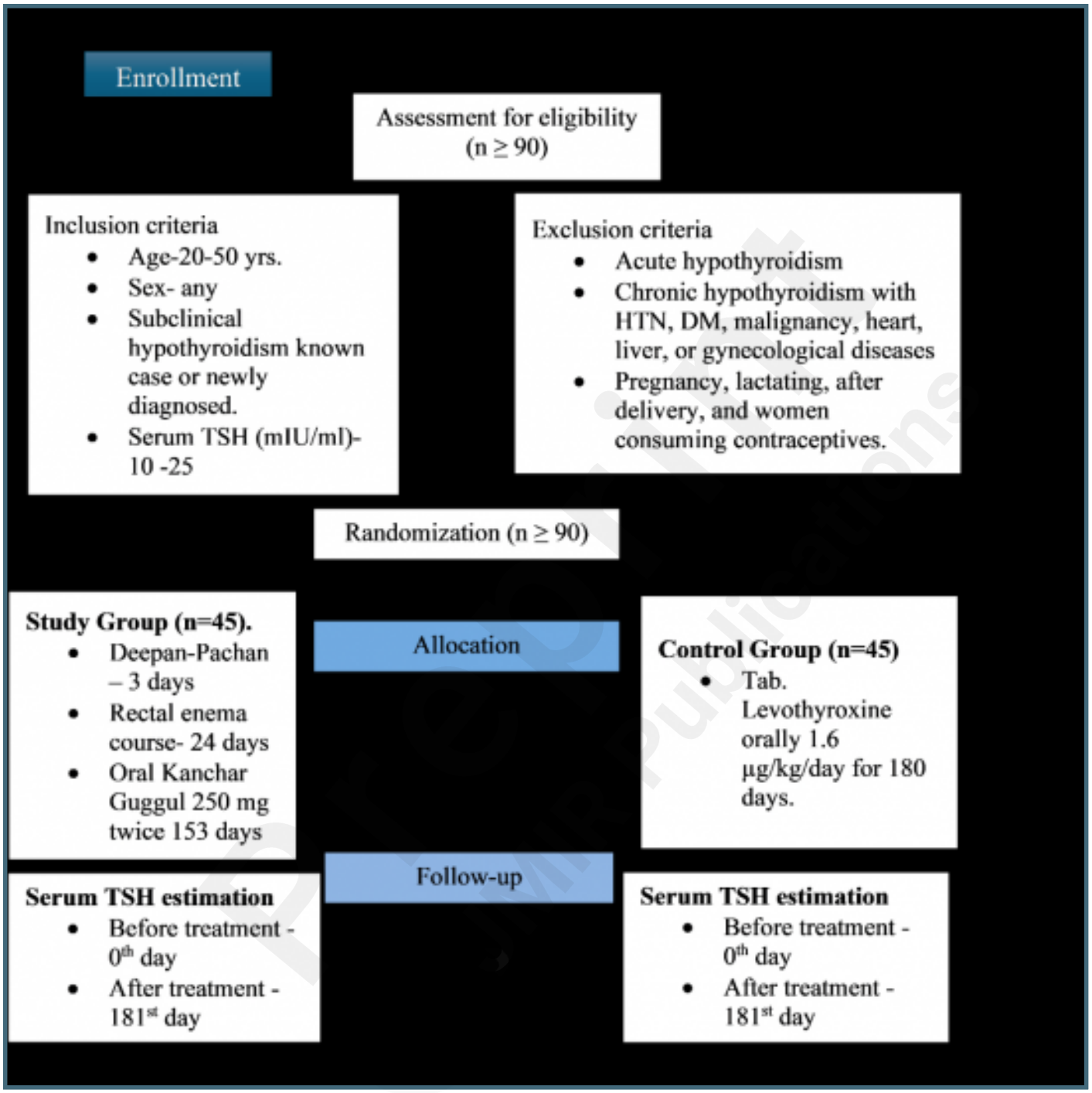
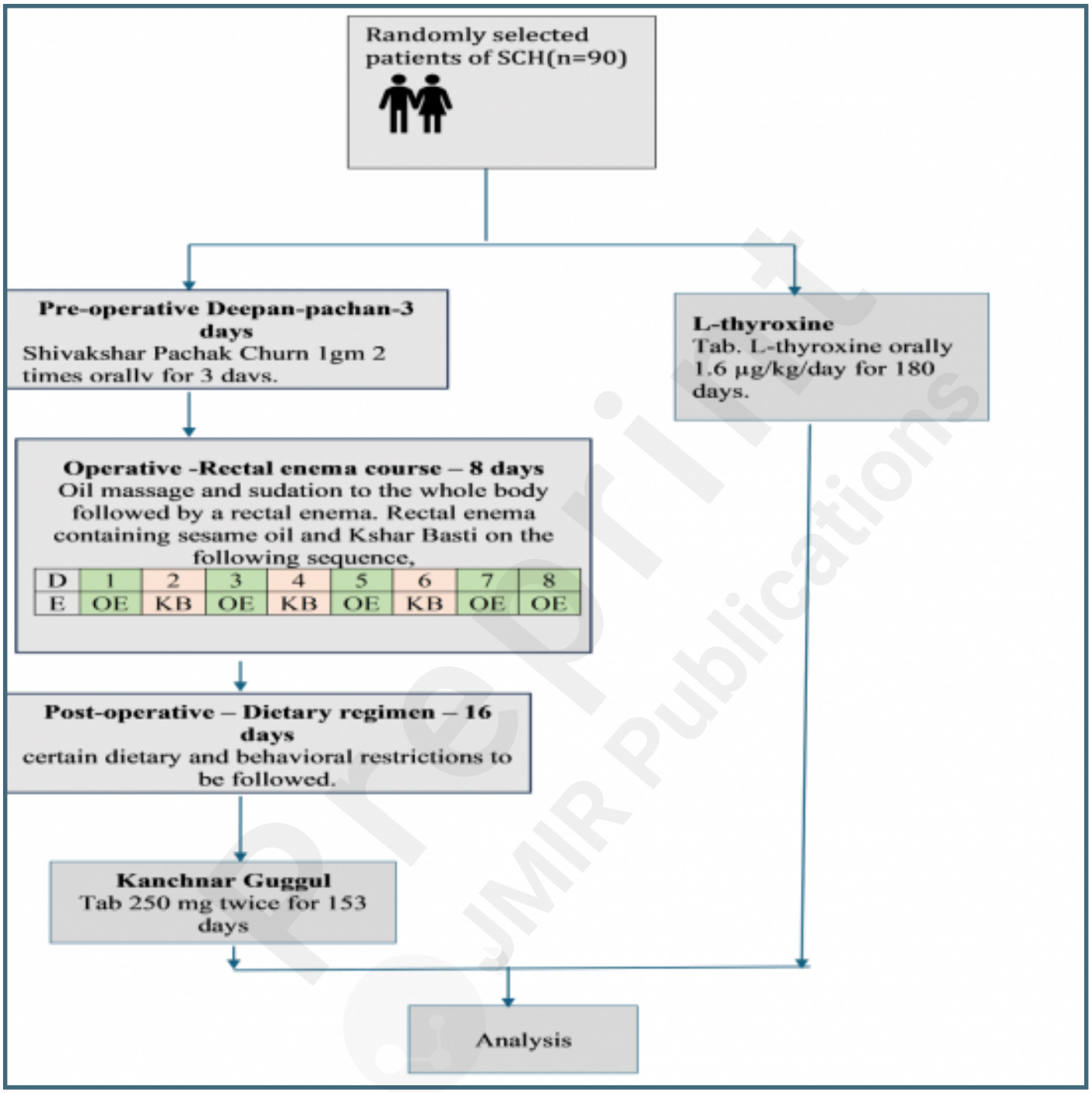
Figures

Study design.



Intervention details.



CONSORT (or other) checklists

SPIRIT checklist.
URL: http://asset.jmir.pub/assets/8472c4f7331036dcae8492200532ded5.pdf