Research Protocol

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Ayurveda Section

Evaluation of Comparative Efficacy of *Ikshvaku Vamana* (*Lagenaria siceraria*) followed by *Nishakatakadi Kashaya Pana* against Standard Control in the Management of Type 2 Diabetes Mellitus (*Sthul Prameha*): A Randomised Controlled Trial Protocol

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ABSTRACT

Introduction: Diabetes Mellitus (DM), particularly Type 2 DM (T2DM), is a metabolic disorder with an increasing global prevalence. Ayurveda correlates T2DM with *Sthul Prameha*, a condition dominated by *Kapha* and *Meda*. Conventional treatments like Metformin manage symptoms but often lead to side-effects and require lifelong use. Ayurveda emphasises Therapeutic Emesis (*Vamana Karma*) for Kapha-dominant diseases. As mentioned in the *Charaka Samhita*, therapeutic emesis using *Lagenaria siceraria* (*Ikshvaku* or bottle gourd) induces *Vamana* without causing exhaustion. *Nishakatakadi* decoction has also shown hypoglycaemic potential.

Need of the study: Diabetes affects 387 million people globally (8.3%) and is projected to reach 592 million by 2035. India has the highest prevalence, with 69 million cases expected to double by 2040. In Ayurveda, *Kapha* is the primary *Dushya* in DM and is best addressed by *Vamana*, especially for obese T2DM patients (*Sthul Prameha*). While Metformin offers symptom management, *Vamana* addresses the root cause by targeting Kapha. Therapeutic emesis (*Vamana Karma*) using *Lagenaria siceraria* (*Ikshvaku* or bottle gourd) is effective in inducing *Vamana* without significant exhaustion, making it ideal for DM patients. However, clinical trials validating these therapies are scarce.

Aim: To evaluate the comparative efficacy of *Ikshvaku Vamana* (using *Lagenaria siceraria*) followed by *Nishakatakadi Kashaya Pana* against standard control in T2DM (*Sthul Prameha*).

Materials and Methods: A randomised single-blind two-arm superiority control trial will be conducted at Mahatma Gandhi Ayurveda College Hospital and Research Centre, Wardha Maharashtra, India, from January 2025 to January 2026. Sixty patients will be divided into two groups: Group A (n=30): Standard treatment with Metformin (500 mg BD for 28 days). Group B (n=30): Therapeutic emesis (*Vamana Karma*) using *Lagenaria siceraria* (*Ikshvaku* or bottle gourd) followed by *Nishakatakadi* decoction for 14 days. Objective parameters (Fasting Blood Sugar (FBS): 126-200 mg/dL, Postprandial Blood Sugar (PPBS): 140-300 mg/dL, Body Mass Index (BMI) ≥25) will be assessed on days 0, 14, and 28 for both groups. Data will be analysed using paired and unpaired t-tests, with p-value <0.05 considered significant.

Keywords: Diabetes, Glucose, Insulin, Lifestyle disorders, *Madhumeha, Panchkarma, Santarpana, Shodhana*, Sugar

INTRODUCTION

The T2DM, referred to as *Sthul Prameha* [1] in Ayurveda (Obese DM), is a significant global health issue. It is characterised by persistent hyperglycaemia due to impaired insulin secretion, insulin action, or both. This condition, often termed the "silent killer," negatively impacts the quality of life and contributes to severe complications, including nephropathy, retinopathy, and cardiovascular disorders. According to the International Diabetes Federation (IDF), T2DM is expected to become more common worldwide, with 537 million individuals affected globally, or 10.5% of all adults in the 20-79 years age group [2]. While modern treatments like Metformin and insulin are widely available, they face limitations such as drug resistance, adverse effects, and high costs, leaving many challenges unaddressed.

In Ayurvedic texts, *Prameha* is described as a syndrome marked by excessive urination and turbidity of urine, often associated with imbalances in *Kapha, Pitta*, and *Meda Dhatus* (bodily humours). Among the various subtypes, *Sthul Prameha* (Obese patient of DM) corresponds closely to T2DM, where the predominance of *Kapha Dosha* leads to systemic derangements. Ayurveda offers a holistic approach incorporating dietary and lifestyle modifications (*Dincharya*—Daily Routine and *Ritucharya*—Seasonal Regimen), herbal formulations, and *Panchakarma* therapies to manage this condition. Therapeutic Emesis, one of the Panchakarma therapies, is highly effective in addressing *Kapha Dosha* imbalances. Among the various emetic formulations, therapeutic emesis (*Vamana Karma*) using *Lagenaria siceraria* (Ikshvaku or bottle gourd) [3], a well-documented drug and procedure in Ayurveda, is known for its potent yet gentle emetic action without causing excessive exhaustion [4]. This makes it ideal for patients with *Kapha*-dominant disorders like *Sthul Prameha*. Furthermore, *Nishakatakadi Decoction* [5], a classical polyherbal formulation, has shown promising antidiabetic, anti-inflammatory, and *Kapha-Pitta* pacifying properties in clinical and preclinical studies.

The current study aims to evaluate the comparative efficacy of therapeutic emesis (*Vamana Karma*) using *Lagenaria siceraria* (Ikshvaku or bottle gourd) followed by *Nishakatakadi* Decoction consumption against standard allopathic treatment (Metformin) in managing T2DM. By integrating traditional Ayurvedic therapies with evidence-based research, this study seeks to provide an effective, holistic, and sustainable treatment alternative for T2DM, addressing glycaemic control and associated metabolic derangements.

Objectives

Primary objectives:

1. To assess the efficacy of therapeutic emesis (*Vamana Karma*) using *Lagenaria siceraria* (Ikshvaku or bottle gourd) followed by *Nishakatakadi Kashaya* in reducing blood sugar levels.
2. To compare the efficacy of therapeutic emesis (*Vamana Karma*) using *Lagenaria siceraria* (*Ikshvaku* or bottle gourd) followed by *Nishakatakadi Kashaya* against standard control in reducing blood sugar levels.
3. To assess the efficacy of the standard control in reducing blood sugar levels.

Secondary objectives: To evaluate the reduction in lipid profile levels in the intervention group (therapeutic emesis using Lagenaria siceraria [*Ikshvaku* or bottle gourd] + *Nishakatakadi Kashaya*) compared to the standard control group.

REVIEW OF LITERATURE

T2DM, characterised by sustained hyperglycaemia due to insulin resistance or insufficient secretion, closely correlates with *Madhumeha* in Ayurveda, particularly *Sthula Prameha* (Obese patients with DM). This condition, marked by the vitiation of *Kapha* and *Meda*, demands depleting therapies (*Aptarpana*) such as detoxification and palliative treatments to alleviate metabolic imbalances. Ayurvedic formulations like *Nishakatakadi* decoction and interventions such as *Ikshvaku* Emesis (*Lagenaria siceraria*) are traditionally employed to reduce *Kapha*, enhance digestive fire, and improve glycaemic control. Comparative studies highlight the efficacy of these treatments in managing BMI, relieving symptoms, and offering holistic benefits alongside conventional therapies like Metformin. However, further research is warranted to substantiate these findings [6].

Ayurveda identifies prediabetes as a condition resembling the premonitory stage (*Purva Roopa*) [7] of *Prameha*, a *Kapha-Meda* dominant disorder. It is considered a reversible stage with a good prognosis, requiring timely interventions like detoxification therapies to prevent disease progression. Therapeutic emesis is highlighted as the primary treatment for conditions involving excessive *Kapha*, *Meda*, and *Kleda* (bodily humours). A comparative study of *Madanaphala* and other emetic (*Vamaka*) drugs showed that both effectively lowered fasting blood glucose, postprandial blood glucose levels, and HbA1c levels. However, *Madanaphala* was more efficacious in achieving procedural ease and superior clinical outcomes. These findings emphasise the significance of personalised Ayurvedic treatments in managing metabolic conditions like prediabetes while addressing underlying pathophysiological imbalances [4].

Madhumeha, described in Ayurveda as a *Vata-Kapha* dominant disorder, closely resembles T2DM. It is considered a *Bahudosha Vyadhi* caused by improper diet, a sedentary lifestyle, and metabolic imbalances leading to elevated blood sugar levels and associated complications. Detoxification is emphasised for managing *Madhumeha*, as it addresses the root cause by eliminating vitiated Doshas. Among the detoxification procedures, *Nitya Virechan* (daily therapeutic purgation) using herbal formulations like *Argwadha Kwatha* and *Nishakatakadi Kwatha* has shown promising results in managing hyperglycaemia and improving metabolic health. Studies have highlighted the hypoglycaemic properties of *Nishakatakadi Kwatha* and its efficacy in reducing fasting blood glucose, postprandial blood glucose levels, and HbA1c levels. Similarly, *Argwadha Kwatha* has demonstrated effectiveness as a mild purgative for regulating blood glucose levels and alleviating symptoms such as frequent urination, excessive thirst, and fatigue. These interventions reflect the potential of integrating Ayurvedic therapies into the holistic management of diabetes [8].

Hypothesis

Null hypothesis (H_0): There is no significant reduction in blood glucose levels by therapeutic emesis *(Vamana Karma)* using *Lagenaria siceraria* (*Ikshvaku* or bottle gourd) followed by *Nishakatakadi Kashaya Paan* than Standard Control treatment in T2DM *(Sthul Prameha)*

Alternative hypothesis (H_1): There is significant reduction in blood glucose levels through therapeutic emesis (*Vamana Karma*) using Lagenaria siceraria (*Ikshvaku* or bottle gourd) followed by *Nishakatakadi Kashaya Paan* compared to standard control treatment in T2DM (*Sthul Prameha*).

MATERIALS AND METHODS

A randomised, single (assessor)-blind, double-arm superiority control trial will be conducted at Mahatma Gandhi Ayurveda College Hospital and Research Centre, Salod, Wardha, Maharashtra, from January 2025 to January 2026. Ethical approval has been obtained from the Institutional Ethics Committee of the same institute under registration number MGACHRC/IEC/Jun-2024/844. The trial is registered on the CTRI website under registration number CTRI/2024/09/073888. The Institutional Ethics Committee will oversee the trial's progress and finalise its outcomes. [Table/Fig-1] below presents the schedule to be followed in the intervention group [9].

Day	Schedule	Medicine - Name, Dose, and Duration
Day-0	Baseline assessment	(Before treatment assessment)
Day-1	*Deepana Pachana* (Digestive and Carminative Therapy)	With *Chitrakadi* tablets 2-tab BD with lukewarm water (before food)
Day-2		
Day-3		
Day-4	*Snehapana*	50 mL *Gau Ghruta paan* (drinking of Cow's Ghee)
Day-5		100 mL *Gau Ghruta paan* (drinking of Cow's Ghee)
Day-6		150 mL *Gau Ghruta paan* (drinking of Cow's Ghee)
Day-7	Vishram Din (*Snehana Swedana (Fomentation Therapy)*	*Kapha Utkleshakara Ahara Vihara*
Day-8	*Sarvanga Snehana Swedana (Fomentation Therapy)* followed by *Vamana Karma (Therapeutic Emesis)*	*Ikshvaku Yoga* {*Antarnakha Mushti Pramana (Quantity Measured by Fist Without Nails)*}
Day-9	*Sansarjana Krama (Post-Emesis Dietary Regimen)* for five days	As mentioned in Ayurveda Classical Texts
Day-10		
Day-11		
Day-12		
Day-13		
Day-14	Assessment	(After treatment assessment)
Day14 - 28	*Shaman Chikitsa*	*Nishakatakadi Kashaya* [9] *(Decoction) Paan* - 30 mL BD
Day-28	Follow-up	Follow-up assessment

[Table/Fig-1]: Schedule to be followed for therapeutic emesis (*Vamana Karma*) using *Lagenaria siceraria* (*Ikshvaku* or bottle gourd).

Criteria for Selection of Patients:

Inclusion criteria:

1. Patients willing to provide written informed consent.
2. Patients of either gender aged between 25 and 55 years.
3. Patients fit for *Vamana Karma* (Therapeutic Emesis) — Vamya (eligible for therapeutic emesis).
4. Newly diagnosed patients with T2DM (*Sthul Prameha*).
5. Patients with fasting blood sugar levels of 126-200 mg/dL and postprandial blood sugar levels of 140-300 mg/dL [10].

Exclusion criteria:

1. Patients unfit for *Vamana — Avamya* (not eligible for therapeutic emesis).
2. Patients with known cases of cancer, tuberculosis, cardiac disorders, hernia, thyroid disorders, hypertension, gestational diabetes, etc.
3. Pregnant and lactating women.
4. Patients with Type I diabetes or insulin-dependent diabetes.
5. Patients with complications of diabetes such as nephropathy, diabetic foot, retinopathy, carbuncles, etc.

Assessment Criteria

Screening parameters:

1. Fasting blood sugar: 126-200 mg/dL [10]
2. Postprandial blood sugar: 140-300 mg/dL [10]
3. BMI: equal to or greater than 25 [11]
4. Lipid profile levels [12]:
   - Serum cholesterol: 200-239 mg/dL
   - Serum triglycerides: 150-199 mg/dL
   - Serum High Density Lipoprotein (HDL): >60 mg/dL
   - Serum Low Density Lipoprotein (LDL): >159 mg/dL
   - Serum Very Low Density Lipoprotein (VLDL): >30 mg/dL

Criteria for Ending or Changing Allocated Interventions

1. Patients will be withdrawn if fasting blood sugar exceeds 200 mg/dL or postprandial blood sugar exceeds 300 mg/dL.
2. Patients who choose to withdraw from the study will be permitted to do so and will be replaced.
3. Patients will be withdrawn if they develop any acute illness during the trial that may interfere with the study.
4. In the event of untoward incidents, drug sensitivity, or any other health issue during the trial, the patient will be provided free treatment until the issue is resolved. Such patients will also be withdrawn and replaced.

Calculation of the sample size: The sample size is calculated for comparing two means — pre- and post-evaluation of fasting plasma glucose levels (mg/dL) [7].

Formula- $$n = \frac{\{(Z(1-\alpha/2)+Z(1-\beta)^2 \times (\sigma 1^2 + \sigma 2^2/r)\}}{(\mu 1-\mu 2)^2}$$

Where:

- n: Sample size per group.
- $\sigma 1^2$, $\sigma 2^2$: Variances of Group 1 and Group 2
- r: Ratio - Group-2 to Group 1
- Alpha (α): 0.05 =1.96
- Beta (β): 0.20 =0.84
- BSL-F Mean in group metformin ($\mu 1$) before: 168.73 (As per the reference article used for sample size calculation) [6]
- Standard Deviation in Metformin ($\sigma 1$): 53.49
- Mean in group metformin after ($\mu 2$): 127.8
- Standard deviation in in Metformin ($\sigma 2$): 43.69
- Ratio (Group-2/Group-1): 1

$$n = \frac{\{(1.96) + Z(0.84)^2 \times (53.49^2 + 43.69^2/1)\}}{(168.73-127.8)^2} = 23$$

Study Procedure

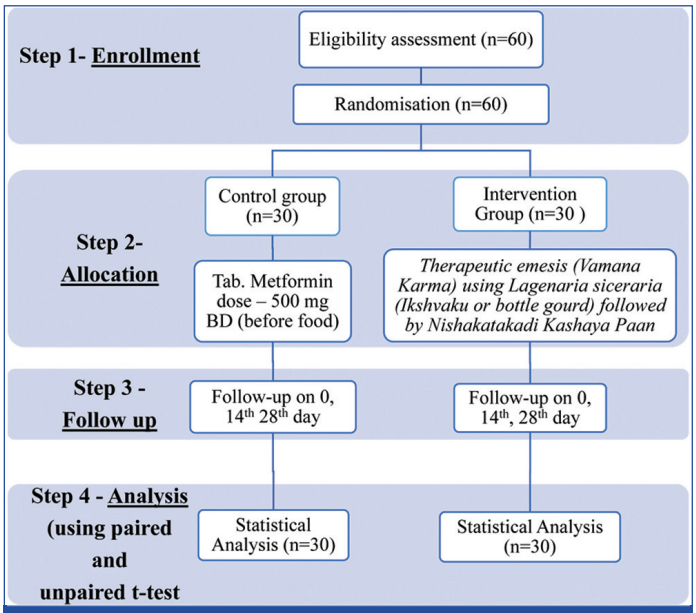
Hence, the minimum sample size needed per group is 23, leading to a total sample size of 46. However, considering possible patient drop-out, we will adjust the sample size per group to 30, resulting in a total sample size of 60.

These sixty patients will be divided into two groups:

Group A (N=30) (Control group) : Standard treatment with Metformin (500 mg BD) before meals for 28 days.

Group B (N=30) (Experimental group): Therapeutic emesis (*Vamana Karma*) using *Lagenaria siceraria* (*Ikshvaku* or bottle gourd) measured by *Antarnakha Mushti Pramana* (quantity as measured by a fist without nails). This will be combined with Vacha (½ of *Ikshvaku*), *Saindhav* (¼ of *Ikshvaku*), and honey as required, followed by a post-emetic dietary regimen (*Sansarjana Krama*) for five days. After this, *Nishakatakadi* decoction will be consumed for 14 days.

Assessments will be conducted on the 0th, 14th, and 28th days for both groups [Table/Fig-2].



[Table/Fig-2]: Research flow diagram (study design in consort form).

The drugs will be procured from a certified retail source and standardised by the Department of Dravya Guna at MGACH&RC, Wardha. Market preparations of Metformin and *Nishakatakadi* decoction will be used.

Details of Drugs Used [Table/Fig-3,4] [13]:

The formulation consists of the following ingredients:

Ikshvaku (Lagenaria siceraria) - Root *(Moola)* - Quantity: *Antarnakha Mushti Pramana*;

Nisha (Haridra) (Curcuma longa Linn.) - Rhizome *(Kanda)* - Quantity: 1 part;

Kataka (Strychnos potatorum Linn.) - Seed *(Beeja)* - Quantity: 1 part;

Name	Taste (Rasa)	Properties (Guna)	Potency (Veerya)	Post digestion effect (Vipaka)	Action (Karma)	Action On Doshas (Doshghnata)
Ikshvaku	*Tikta, Katu*	*Laghu* (lightness), *Ruksha* (Dry), *Tikshna*	*Sheeta*	*Katu*	*Teevra Vamak, Bhedana*	*Kaphaghna, Pittaghna*
Nisha (Haridra)	*Tikta, Katu*	*Ruksha, Laghu*	*Ushna*	*Katu*	*Vedanasthapan, Lekhana*	*Kapha Vata Shamak, Pitta shamaka*
Kataka	*Madhura, Kashaya, Tikta*	*Laghu, Vishada*	*Sheeta*	*Madhura*	*Chakshushya*	*Kaphahara, Vatahara*

Nellika (Amalaki)	*Lavanrahit Panchrasatmak, (Amlapradhan)*	*Guru, Ruksha, Sheeta*	*Sheeta*	*Madhura*	*Dahaprashaman, Chakshushya, Keshya*	*Tridoshahara* (bodily humours) pacifying
Tecchi (Paranti)	*Kashya, Tikta*	*Laghu*	*Sheeta*	*Katu*	*Twak Roga hara*	*Pittahara*
Pacchotti (Lodhra)	*Kashaya*	*Laghu, Ruksha*	*Katu*	*Sheeta*	*Raktastambhan, Shothhara*	*Kaphapitta shamak*
Bhadrika (Goraksha Ganja)	*Tikta, Kashaya*	*Laghu, Tikshna*	*Ushna*	*Katu*	*Ashmari Bhedana*	*Kapha Vata Shamak*
Ekanayaka (Saptarangi/ Saptachakra)	*Kashaya, Tikta*	*Laghu, Ruksha, Tikshna*	*Ushna*	*Katu*	*Shotha hara, Vedanasthapana*	*Kapha Pitta shamak, Vata-udaseen*
Ramaccha (Usheera)	*Tikta, Madhura*	*Ruksha, Laghu*	*Sheeta*	*Katu*	*Dahaprashamana, Swedaapnayana*	*Kapha shamak, Pitta shamak*

[Table/Fig-3]: Showing ayurvedic properties of drugs used [13,14].

Name of the Drug	Latin name	Properties of Drugs Which Break the Disease Pathology
Ikshvaku [15]	*Lagenaria siceraria*	*Kapha and Pitta* are pacifying, anti-inflammatory, antioxidant, antiurolithiasis, antimicrobial, cytotoxic, lipid-lowering, anti-stone, anxiolytic, analgesic, anticancer, diuretic, anthelmintic, and hepatoprotective properties.
Nisha (Haridra) [16]	*Curcuma longa Linn.*	*Tridosha* {(Three Biological Humours *(Vata, Pitta, Kapha)}* pacifying, reversal of insulin resistance, Anti-atherosclerotic, Lipolytic, anticholesterol property, metabolic correction and antioxidant property.
Kataka [17]	*Strychnos potatorum Linn.*	*Kapha-Vata* pacifying, antidiabetic, anticholesteremic, antimicrobial, hepatoprotective activity, antihelmintic, antiulcerogenic, anti-inflammatory, antiarthritic, antinociceptive, analgesic, diuretic, nephroprotective, antioxidant, antianaphylactic activity.
Nellika (Amalaki) [18]	*Emblica officinalis Gaertn.*	*Tridosha* {(Three Biological Humours *(Vata, Pitta, Kapha)}* pacifying, especially *Pittashamaka,* antioxidant, hypolipidemic, immunomodulatory, hypoglycaemic, antioxidant.
Tecchi (Paranti) [19]	*Ixora coccinea L.*	*Pitta pacifying,* antioxidant, antimicrobial, anti-inflammatory, antifungal.
Pacchotti (Lodhra) [20]	*Symplocos racemosa Roxb.*	*Kapha*-pitta pacifying, antimicrobial, antibacterial, anticancer, lipid-lowering.
Bhadrika (GorakshaGanja) [21]	*Aerva lanata (L) Juss. Ex. Schult*	*Kapha-Vata pacifying,* anti-inflammatory, antimicrobial, anthelminthic, and antitumour activities.
Ekanayaka (Saptarangi/ Saptachakra) [22]	*Salacia chinensis Linn.*	*Kapha-Pitta* pacifying, antihypertrophic, antifibrogenic effect, antioxidant, anti-inflammatory, antiobesity agent, hepatoprotective, antiproliferative, antimicrobial.
Ramaccha (Usheera) [23]	*Vetiveria zizanioides (Linn.) Nash.*	*Kapha-Pitta* pacifying, antioxidant, antimicrobial, antifungal, and anti-inflammatory activities.

[Table/Fig-4]: Role of Ikshvaku and Nishakatakadi decoction based on properties of each component [15-23].

Nellika (Amalaki) (Emblica officinalis Gaertn.) - Fruit *(Phala)* - Quantity: 1 part;

Tecchi (Paranti) (Ixora coccinea L.) - Root *(Moola)* - Quantity: 1 part;

Pachotti (Lodhra) (Symplocos racemosa Roxb.) - Stem Bark *(Kanda Twak)* - Quantity: 1 part;

Bhadrika (Aerva lanata (L) Juss.ex. Schult) - Rhizome *(Moola)* - Quantity: 1 part;

Ekanayaka (Saptarangi/Saptachakra) (Salacia chinensis Linn.) - Root *(Moola)* - Quantity: 1 part;

Ramaccha (Usheera) (Vetiveria zizanioides (Linn.) Nash.) - Root *(Moola)* - Quantity: 1 part;

Jala (Water) - Quantity: 8 times (64 parts).

[Table/Fig-3] mentions the rasa, guna, virya, vipaka, and karma of these drugs, while [Table/Fig-4] shows the properties of these drugs that help to mitigate the disease pathology [15-23].

STATISTICAL ANALYSIS

The data will be analysed using Statistical Package for the Social Sciences (SPSS) version 17.0 software. Changes in fasting and postprandial blood sugar levels will be evaluated within both the intervention and control groups using paired t-tests. In contrast, unpaired t-tests will be applied to compare differences between the groups. A p-value <0.05 will be considered statistically significant.

Intervention modification: Authors will notify the ethical committee of any unfavorable side-effects. Patients will receive treatment for any negative effects. If participants choose to discontinue treatment, they must provide an explanation.

OUTCOMES

Primary outcome:

1. Reduction in blood sugar levels (FBS, PPBS, HbA1c) in the intervention group (therapeutic emesis using *Lagenaria siceraria* [*Ikshvaku* or bottle gourd] + *Nishakatakadi Kashaya*) compared to the standard control group.
2. Reduction in blood sugar levels (FBS, PPBS, HbA1c) within each group individually (intervention and control) over time.

Secondary outcomes:

1. Reduction in lipid profile levels in the intervention group (therapeutic emesis using *Lagenaria siceraria* [*Ikshvaku* or bottle gourd] + *Nishakatakadi Kashaya*) compared to the standard control group.
2. Assessment of any adverse effects or complications resulting from the interventions.

The participants' timeline has been tabulated in [Table/Fig-5].

Scholar/Investigator	Dr. Garima Gupta							
Title	Evaluation of the Comparative Efficacy of *Ikshvaku Vamana* (*Lagenaria siceraria*) followed by *Nishakatakadi Kashaya Pana* against Standard Control in the Management of T2DM (*Sthul Prameha*)							
Steps	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8
IEC authorisation								
Literature overview								
Medicinal preparation								
Patients enrolled								
Data collection								
Analysis								
Thesis writing								
Submission								

[Table/Fig-5]: Participant timeline (Gantt Chart).

Recruitment: Patients with newly diagnosed T2DM (*Sthul Prameha*) will be selected by Mahatma Gandhi Ayurveda College, Hospital and

Research Centre, Salod, Maharashtra, India from the Panchakarma Department and specialised peripheral camps. There will be 60 volunteers for the experiment.

Allocation implementation: The original author or the researcher will enroll the participants, administer the intervention, and determine the allocation sequence.

Blinding: A randomised single-assessor blind double-arm superiority comparative control trial will be conducted.

Dissemination: This procedure will also be made available as a thesis to promote research. This study protocol includes a discussion of the methodology, data-gathering strategies, data-processing tactics, and ethical approval. Authors aim to expand the body of knowledge in this field and facilitate further research.

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