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Research Protocol

Ayurveda Section

Comparative Efficacy of KP (*Kantak Panchamoola*) Decoction Enema followed by KP Tablet (*Vati*) versus Standard Treatment in Type 2 Diabetes Mellitus (*Prameha*): A Randomised Controlled Trial Research Protocol

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ABSTRACT

Introduction: Diabetes Mellitus (DM) is a metabolic disease characterised by elevated blood sugar levels resulting from either inadequate insulin synthesis or compromised insulin activity, which can lead to organ damage. The prevalence of Type 2 DM (T2DM) is expected to rise globally. In traditional medicine, *Prameha* is a term used in Ayurveda to describe conditions involving metabolic dysfunctions, which aligns with diabetes. Congenital *Prameha* is comparable to Type 1 DM (T1DM), while lifestyle-induced *Prameha* corresponds to T2DM. Ancient Ayurvedic texts detail symptoms of *Prameha* that closely resemble those of modern diabetes, such as frequent urination, fatigue, and systemic metabolic disturbances.

Need for the study: Traditional hypoglycaemic drugs often lead to weight gain and other adverse effects, creating a demand for safer alternatives. Ayurveda provides solutions through *Panchakarma* and herbal medicines, notably *Basti* (medicated enema), a holistic and non invasive treatment. This study examines *Kantaka panchamoola Basti*, a cost-effective option for Ayurvedic diabetes management. *Kantaka panchamoola* is known for its diuretic, anti-inflammatory, and metabolic benefits, helping to regulate metabolism and improve insulin sensitivity, making it suitable for *Prameha* treatment. Despite the wealth of literature on Ayurveda and diabetes, research on *Basti* is limited.

Aim: To evaluate the comparative efficacy, safety and affordability of KP decoction enema followed by KP tablet versus standard treatment (Tab. Metformin) in managing T2DM (*Prameha*).

Materials and Methods: A randomised, open-label, standard-controlled trial will be conducted at Mahatma Gandhi Ayurved College Hospital and Research Centre, Salod, Wardha, Maharashtra India, from May 2025 to May 2026. Sixty patients will be divided into two groups. Group A (N=30) will be prescribed Tab. Metformin for a consecutive 48 days, while Group B (N=30) will receive KP decoction enema for 16 days, followed by KP tablet for 32 days. Therapeutic outcomes will include a reduction in blood sugar levels (both fasting and postprandial) as well as urine sugar levels. Statistical analysis will be conducted using Statistical Package for the Social Sciences (SPSS) 17.0 Software. The independent samples t-test will be used for comparison of baseline characteristics between groups, and the paired t-test will be used for within-group comparison. A p-value of <0.05 will indicate a significant difference between the groups.

Keywords: Fasting blood glucose, Herbal medicines, Hyperglycaemia, *Panchkarma*

INTRODUCTION

A metabolic disorder known as DM is characterised by persistently high blood sugar levels caused by insufficient insulin production or action. Chronic hyperglycaemia from DM can harm organs such as the kidneys, heart, eyes, and nerves, leading to dysfunction and failure [1]. The fundamental issue lies either in a lack of insulin or the body's inability to respond adequately to insulin. Autoimmune diseases and certain infections can impair the pancreas's ability to produce insulin.

While there are various forms of diabetes, Type 1 and Type 2 are the most common [2]. Fasting Plasma Glucose (FPG), Postprandial Plasma Glucose (PPG), and HbA1c are used to measure glycaemic levels in individuals with normal, prediabetic, and diabetic conditions. According to the International Diabetes Federation (IDF), T2DM is expected to become more prevalent worldwide; 537 million people globally, or 10.5% of all adults aged 20 to 79, have the disease [3]. In 2014, diabetes affected 8.5% of individuals over the age of 18 years. By 2019, diabetes was directly responsible for 1.5 million deaths, with 48% occurring in people younger than 70 years. Furthermore, diabetes contributed to 460,000 deaths from kidney disease, and 20% of deaths from cardiovascular disease were linked to elevated blood glucose levels [4].

Diabetes is recognised as a metabolic disease associated with lifestyle choices. The malfunction of various body components, including the three bio-energies (*Vata, Pitta, and Kapha*), fat, fluid, plasma, muscle, blood, reproductive fluids, lymph, and vital energy (immunity), is one of the significant disorders mentioned in ancient Ayurvedic literature (*Charaka*). There are two forms of diabetes: lifestyle-induced diabetes and congenital diabetes, also known as genetic or hereditary diabetes [5], which correlate with modern classifications of DM [6].

According to Ayurvedic texts, *Prameha* has symptoms resembling those of DM syndrome, including increased urine production, polyuria, and cloudiness of urine [7]. In response to the rising global prevalence of diabetes, integrative approaches combining traditional Ayurvedic therapies with modern medicine are gaining attention.

One such approach involves the use of *Kantaka Panchamoola* medicated enema (KP Basti) alongside conventional antidiabetic treatments.

The *Kantaka* group, also referred to as *Kantak Panchamoola*, consists of five medicinal plants: *Karmarda* (*Carrisa carandas*), *Gokshura* (*Tribulus terrestris*), *Saireyaka* (*Barleria prionitis*), *Shatavari** (*Asparagus racemosus*), and *Grudhranakhi* (*Argemone Mexicana*). These herbs are recognised in Ayurveda for their therapeutic effects in managing inflammatory conditions, bleeding disorders, urinary tract diseases, diabetes, and reproductive system imbalances [8].

Their pharmacological actions include anti-inflammatory, antioxidant, diuretic, and hormone-modulating properties. Particularly relevant to diabetes, these herbs support metabolic regulation by promoting urinary clearance, reducing blood glucose levels, and protecting against oxidative stress-related complications. Additionally, they help restore balance in reproductive tissues and maintain systemic equilibrium.

When administered through a medicated enema, this formulation enables direct and efficient absorption, bypassing liver metabolism and enhancing bioavailability [9]. This integrative method holds promise for improving glycaemic control and overall metabolic health in individuals with diabetes, supporting a holistic approach to long-term management.

REVIEW OF LITERATURE

Acharya Susruta has identified five medicinal plants under the category of *Kantaka Panchmoola: Karmarda* (*Carissa carandas*), *Gokshura* (*Tribulus terrestris*), *Saireyaka* (*Barleria prionitis*), *Shatavari* (*Asparagus racemosus*), and *Hinstra* (*Capparis sepiaria*). These plants are collectively termed *Kantaka Panchmoola* due to their thorn-bearing nature (*Kantaka*). The roots (*Moola*) of these herbs are utilised in medicinal formulations. Most of these herbs exhibit *Madhura Rasa*, except for *Karmarda*, which possesses *Amla Rasa*, and *Hinstra*, which has *Tikta Rasa*. Therefore, the collective *Rasa* of *Kantaka Panchmoola* is identified as *Amla*, *Madhura*, *Tikta*, and *Katu* [9]. Each of these herbs provides unique therapeutic properties that support the management of *Prameha* [9]. An analysis of *Kantaka Panchmoola* suggests that this formulation holds promise in addressing *Prameha*. Each herb contributes specific therapeutic effects targeting key pathophysiological aspects such as blood sugar regulation, oxidative stress reduction, diuresis, and inflammation control [10].

Chhatre S et al., demonstrated that saponins from *Tribulus terrestris* (TT) exhibited strong hypoglycaemic properties in alloxan-induced diabetic mice. Treatment with TT led to reduced serum glucose, triglycerides, and cholesterol, along with enhanced Serum Superoxide Dismutase (SOD) activity, indicating potent antioxidative effects. The ethanolic extract of TT was found to inhibit gluconeogenesis and oxidative stress, likely through α-glucosidase and aldose reductase inhibition. Additionally, the TT extract demonstrated cardioprotective benefits, making it a valuable candidate for managing diabetes with cardiovascular complications [11].

Sharma A and Sharma DN, examined the antidiabetic effects of *Asparagus racemosus* extract, which enhanced glucose tolerance and mitigated postprandial hyperglycaemia in both normal and diabetic rats. The extract increased unabsorbed sucrose in the gastrointestinal tract, suggesting delayed carbohydrate digestion or absorption, and also promoted glucose transport and insulin action in vitro. In diabetic subjects, it contributed to reduced serum glucose, higher insulin levels, increased liver glycogen, and improved oxidative stress markers [12].

Selvamani P et al., investigated the antidiabetic potential of *Capparis sepiaria* ethanol extract in Streptozotocin (STZ)-induced diabetic rats. A dose-dependent reduction in blood glucose levels was observed at 200 and 300 mg/kg, with results comparable to glibenclamide. The extract appears to stimulate pancreatic β-cells, enhancing insulin secretion. Its efficacy is attributed to its flavonoid and tannin content, known for their antidiabetic and insulinotropic properties [13].

Collectively, these studies highlight that each component of *Kantaka Panchmoola* possesses complementary antidiabetic mechanisms, including hypoglycaemic effects, insulin secretion stimulation, inhibition of glucose absorption, antioxidant activity, and enzyme regulation associated with carbohydrate metabolism. Consequently, the present study aims to evaluate the combined efficacy of *Kantaka Panchmoola* by comparing its decoction enema and tablet formulations with standard Metformin therapy for diabetes management.

Objectives:

- To assess the efficacy of *Kantaka Panchmoola* (KP) decoction enema followed by KP tablet on blood sugar levels (fasting and postprandial), urine sugar levels, and HbA1c in T2DM.
- To assess the efficacy of Metformin tablets on blood sugar levels (fasting and postprandial), urine sugar levels, and HbA1c in T2DM.
- To compare the efficacy of KP decoction enema followed by KP tablet with Metformin tablets on blood sugar levels, urine sugar levels, and HbA1c in T2DM.

Null Hypothesis (H_0): There will be no significant difference in the efficacy of *Kantaka Panchmoola* (KP) decoction enema followed by KP tablet (*Vati*) compared to the standard treatment in the management of T2DM (*Prameha*).

Alternate Hypothesis (H_1): There is a significant difference in the efficacy of *Kantaka Panchmoola* (KP) decoction enema followed by KP tablet (*Vati*) compared to the standard treatment in the management of T2DM (*Prameha*).

MATERIALS AND METHODS

A randomised open-label standard-controlled trial will be conducted at Mahatma Gandhi Ayurved College Hospital and Research Centre, Salod (H), Wardha, Maharashtra India, from May 2025 to May 2026. Ethical approval has been obtained from the Institutional Ethics Committee (IEC) of the Mahatma Gandhi Ayurveda College Hospital and Research Centre, Salod (H), Wardha, with registration number MGACHRC/IEC/Jun-2024/843. The trial is registered on the CTRI website with the number CTRI/2024/07/071096. The committee will oversee the trial's progress and determine its conclusion. Therapeutic outcomes will include reductions in blood sugar levels (fasting and postprandial) and urine sugar levels.

Inclusion criteria:

- Patients aged between 20 and 60 years who are willing to give written informed consent.
- Individuals diagnosed with uncomplicated T2DM (NIDDM) within the last six months.
- Fasting blood sugar levels between 126 and 200 mg/dL and postprandial blood sugar levels between 140 and 300 mg/dL [14].
- Patients with T2DM for six months who are not on any other antihypoglycaemic medications.
- Diabetic patients with controlled hypertension, with Systolic Blood Pressure (SBP) ≤140 mmHg and Diastolic Blood Pressure (DBP) ≤90 mmHg (average).
- Patients eligible for the decoction enema procedure as per traditional guidelines [15].
- Newly diagnosed diabetic patients who are unwilling to take allopathic medications.

Exclusion criteria:

- Patients with Insulin Dependent DM (IDDM) or Type 2 Diabetes on insulin therapy.

- Patients with Juvenile Diabetes or Gestational Diabetes.
- Patients with impaired glucose tolerance.
- Patients with diabetes-related complications, such as retinopathy, nephropathy, neuropathy, or a previous history of diabetic coma.
- Patients suffering from any current acute illness or uncontrolled hypertension.
- Pregnant or lactating women.

Criteria for ending or changing allocated interventions:

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

Sample size: The sample size was calculated for comparing two means before and after fasting blood glucose levels (mM).

The formula for calculating the sample size for comparing two independent means is:

$n \geq \{(Z_{(1-\alpha/2)}+Z_{(1-\beta)})^2 (\sigma_1^2+(\sigma_2^2/r))\}/(\mu1-\mu2)^2$

Input parameters:

Z Alpha (α): 0.05= 1.96

Z Beta (β): 0.05= 0.84

Fasting blood glucose level (Mm) before (μ1) in metformin=8.539

Standard Deviation (σ1): 1.632

Fasting blood glucose level (Mm) after (μ2) in metformin (μ2)= 7.004

Standard deviation (σ2): 1.405, Ratio (Group-2/Group-1): 1 [16]

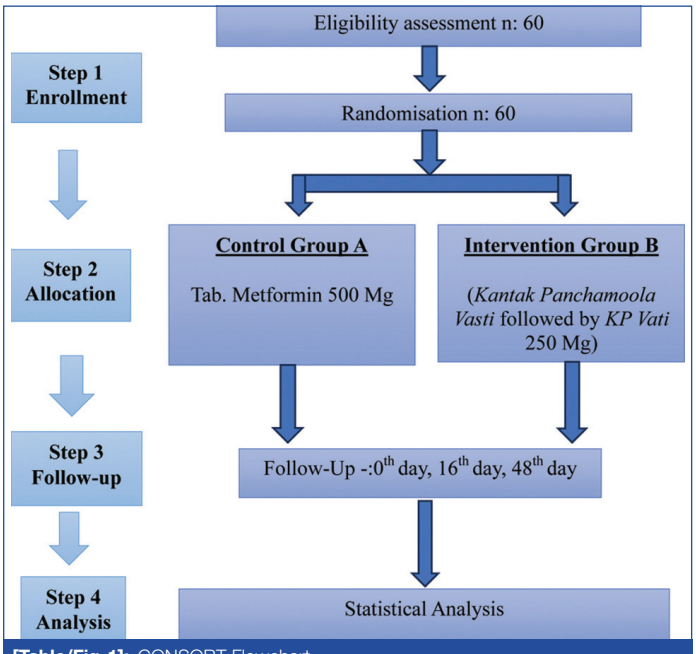
$n \geq 25.6$

Final result:

Minimum sample size per group: 26

Total sample size: 52

Considering a 15% dropout rate, a total of 60 patients will be enrolled in the study. These participants will be randomly assigned to two groups of 30 each [Table/Fig-1] shows CONSORT flowchart. As shown in [Table/Fig-2], Group A (n=30) will receive Tab. Metformin administered daily for 48 consecutive days. Group B (n=30) will be administered KP decoction as an enema for the first 16 days, followed by KP tablets for the remaining 32 days.



[Table/Fig-1]: CONSORT Flowchart.

Detail of drug preparation: The KP decoction enema will be prepared in the Department of Panchakarma as needed, following the procedures prescribed in the ancient texts of Ayurveda [17]. The KP tablet [18] will be prepared at Dattatraya Rasashala, Mahatma Gandhi Ayurved College Hospital and Research Centre, Salod (H), Wardha. Tab. Metformin will be procured from Lifestyle Pharmacy, Sawangi, Wardha.

The preparation will consist of 5 grams of powdered roots from each of the following drugs: *Karmarda* (*Carissa carandas* Linn.), *Gokshura* (*Tribulus terrestris* Linn.), *Saireyaka* (*Barleria prionitis* Linn.), *Shatavari* (*Asparagus racemosus*), and *Grudhranakhi* (*Capparis sepiaria* Linn.). The properties of the drugs in *Kantaka Panchmoola* are detailed in [Table/Fig-3] [19].

Administration of decoction enema: The administration will follow a structured process:

1. Preprocedure (*Poorvakarma*):

- Essential instruments will be gathered, and additional decoctions will be prepared for any complications.
- The patient will undergo an assessment. *Kantak Panchmoola* drugs will be boiled, and the resulting decoction will be mixed with honey, rock salt, sesame oil, and pastes.

2. Patient preparation (*Atur Siddhata*):

- The patient will consume a light meal, stay hydrated, and take short walks.
- Oil massage and mild heat therapy will be administered to aid detoxification.

3. Main procedure (*Pradhanakarma*):

- The patient will be positioned in the left lateral position.
- The anal region will be lubricated, and a catheter will be inserted.
- Lukewarm medicated oil will be administered, and the enema is expected to be expelled within 48 minutes.

4. Postprocedure (*Paschatkarma*):

- The patient will rest in a supine position, followed by gentle rubbing and a lukewarm bath.
- Activities like excessive ventilation, loud speech, travel, and anger will be advised against [20].

5. Diet and aftercare (*Pathya* and *Anya Vichara*):

- The diet will include light soups, meat broths, and nourishing foods, with lukewarm water for hydration.

Outcomes: The assessment criteria for the study will include monitoring blood sugar levels (both fasting and postprandial), urine sugar levels, and HbA1C levels (with five patients from each group being evaluated for HbA1C). Fasting blood sugar levels will be between 126 to 200 mg/dL, and postprandial blood sugar levels will be between 140 to 300 mg/dL [14]. All parameters will be assessed at baseline (before treatment) and again at the end of the treatment period, after 48 days.

STATISTICAL ANALYSIS

The statistical analysis will be conducted using SPSS 7.0 Software. The independent samples t-test will be used for comparison of baseline characteristics between groups, while the paired t-test will be used for within-group comparison. A p-value of <0.05 will indicate a significant difference between the groups.

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

Group	Sample size	Intervention	Dose and frequency	Medium (*Anupan*)	Duration	Follow-up
A	30	Tab. Metformin	500 mg OD before food	Water	48 days	16th day, 48th day.
B	30	16 Days Decoction enema regime: (KP Decoction enema + Medicated Sesame oil enema) i.e., 3 Decoction enema followed by 1 Medicated oil enema i.e., total of 12 decoction enemas and four medicated oil enemas followed by KP tablet orally for 48 consecutive days.	Decoction enema: 960 mL, Once a day on empty stomach	Not Applicable for Decoction enema.	48 days	16th day, 48th day.
			Medicated oil enema: 60 mL, Once a day after food	Not Applicable for Medicated oil enema.		
			250 Mg 3 Tabs BD after food	Luke Warm Water		

[Table/Fig-2]: Showing grouping and posology along with treatment period and follow-up period.

S. No.	Name	Taste (*Rasa*)	Properties (*Guna*)	Potency (*Veerya*)	Post digestion effect (*Vipaka*)	Action (*Karma*)
1	*Karmarda* (*Carissa carandas Linn.*)	Sour (*Amla*)	Light (*Laghu*), Dry (*Ruksha*)	Hot (*Ushna*)	Pungent (*Katu*)	Pacifies *Rakta Pitta*, Heart Tonic (*Hridya*), Emetic (*Vamak*), Diuretic (*Mutrajanana*)
2	*Gokshura* (*Tribulus terrestris Linn.*)	Sweet (*Madhura*)	Heavy (*Guru*), Unctuous (*Snigdha*)	Cold (*Sheeta*)	Sweet (*Madhura*)	Diuretic (*Mutravirechaniya*), Anti-inflammatory (*Sothahar*), Pacifies *Vata*, Strength-promoting (*Balya*), Aphrodisiac (*Vrishya*)
3	*Saireyaka* (*Barleria prionitis Linn.*)	Bitter (*Tikta*), Sweet (*Madhura*)	Light (*Laghu*)	Hot (*Ushna*)	Pungent (*Katu*)	Hair coloring (*Keshranjaka*), Beneficial for skin diseases (*Kustha*), Treats Gout (*Vatarakta*), Detoxifier (*Visha Nashak*)
4	*Shatavari* (*Asparagus racemosus*)	Sweet (*Madhura*), Bitter (*Tikta*)	Heavy (*Guru*), Unctuous (*Snigdha*)	Cold (*Sheeta*)	Sweet (*Madhura*)	Promotes reproductive fluids (*Shukravardhak*), Rejuvenative (*Rasayana*), Eye tonic (*Netrya*),
5	*Grudhranakhi* (*Capparis sepiaria Linn.*)	Bitter (*Tikta*), Pungent (*Katu*)	Light (*Laghu*), Dry (*Ruksha*)	Hot (*Ushna*)	Bitter (*Katu*)	Reduces swelling (*Sophaghna*), Pacifies *Kapha* and *Vata* (*Kaphavatanashak*)

[Table/Fig-3]: Properties of drugs in *Kantak Panchamoola* [19].

Participant timeline: The Gantt chart has been tabulated in [Table/Fig-4].

Scholar/Investigator	Dr. Akshay Sanjeevkumar Rekhe							
Title	Evaluation of comparative efficacy of KP Decoction enema followed by KP Tablet versus standard treatment in the management of Diabetes Mellitus Type II (*Prameha*)							
Steps	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8
IEC authorisation								
Overview of the literature								
Medicine preparation								
Patients enrolled								
Collection of data								
Analysis								
Writing of thesis								
submission								

[Table/Fig-4]: Gantt chart.

Dissemination: To promote the research, this procedure will also be available as a thesis for evaluating the comparative efficacy of the KP decoction enema followed by KP tablets versus standard treatment in managing T2DM (*Prameha*). The study protocol includes a discussion of the methodology, data-gathering strategies, data-processing tactics, and ethical approval. We hope to expand the corpus of knowledge in this field and facilitate further research.

Guidelines: For the study, SPIRIT Guidelines are being followed.

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