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Research Protocol

Ayurveda Section

Efficacy of *Salmusta* Yoga versus Tablet Metformin in Type 2 Diabetes Mellitus (*Madhumeha*): A Research Protocol for Randomised Controlled Trial

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ABSTRACT

Introduction: Diabetes mellitus is a metabolic disorder that can be correlated with *Madhumeha,* a type of *Prameha* in Ayurveda. This is a *Santarpanajanya Vyadhi* (Diseases caused by overnutrition), caused by *Medo Dushti (*disruption in fat metabolism*)* affecting *Medovaha Strotas*. *Salmusta* yoga, containing *Sal* (*Shorea robusta*), *Musta* (*Cyperus rotundus*), and *Kampillaka* (*Mallotus philippensis*) in *Yogratnakar* for the management of *Prameha* (Diabetes mellitus).

Need of the study: Type 2 Diabetes Mellitus (T2DM) is a rapidly increasing metabolic disorder with significant complications. Although modern treatments like insulin and metformin are effective, long-term use may cause adverse effects and does not fully address underlying metabolic disturbances. In Ayurveda, *Madhumeha* involves *Kapha* predominance, Medo Dushti, and *Agnimandya*, requiring a holistic approach. *Shamana Chikitsa* is preferred when *Shodhana* is not feasible. *Salmusta* yoga, described in *Yogaratnakara*, has *Kapha-Medohara* and *Pramehaghna* properties reported to have antihyperglycaemic effects. However, limited clinical evidence exists, highlighting the need to evaluate its efficacy in managing *Madhumeha*.

Aim: Evaluation of comparative efficacy of *Salmusta* yoga Versus tablet metformin in the management of diabetes mellitus type 2.

Materials and Methods: A single-blind (accessor blind) parallel randomised controlled trial will be conducted at the Mahatma Gandhi Ayurved College Hospital and Research Centre, Salod (H) Wardha, Maharashtra, India, from September 2025 to March 2027. The study involves 64 patients meeting the inclusion criteria, randomly assigned into two groups of 32 each. Group 1 will receive *Salmusta* yoga*,* while Group 2 will receive tablet metformin twice a day for two months. Assessments of fasting and postprandial blood sugar level will be conducted on days 0, 30 and 60. Chi-square test, Student's unpaired, and paired t-test will be used for both descriptive and inferential statistics. A significance level of $p<0.05$ will be applied.

Keywords: Blood glucose, Glucose metabolism disorders, Hyperglycaemia, Insulin resistance

INTRODUCTION

Diabetes mellitus is a chronic metabolic disorder characterised by persistent hyperglycaemia and impairment of carbohydrate, fat, and protein metabolism. Diabetes is a major global health challenge, with an estimated 589 million adults in 2024 living with diabetes, of whom almost one-in-two were undiagnosed. In addition, another 1.1 billion adults worldwide had impaired glucose tolerance or impaired fasting glycaemia, predisposing them to an increased risk of developing T2DM [1]. T2DM can be correlated with *Madhumeha,* a type of *Vataja Prameha* as per Ayurveda*,* due to the resemblance of clinical features. Elevated blood sugar levels caused by either insulin resistance or inadequate insulin are its defining feature [2]. According to *Acharya Charaka*, it is mainly caused by the aggravation of *Kapha Doṣha.* Aetiological factors include intake of *Nava-anna* (newly harvested grains less than one year old), excessive consumption of *Dadhi Varga* (curd and fermented milk preparations), *Mamsa-sevana* (meat intake) of *Anupa*, *Gramya*, and *Audaka* animals (marshy, domestic, and aquatic species-all *Kapha*-promoting), along with indulgence in *Asya-sukha* (sedentary habits such as constant sitting) and *Svapna-sukha* (excessive sleep). These factors collectively vitiated *Kapha Doṣha* and subsequent obstruction (*Srotorodha*) of metabolic pathways, forming the basis of *Prameha Samprapti*. *Prameha* is mainly a *Santarpanajanya Vyadhi*, marked by predominance of *Kapha Doṣha,* vitiation of *Meda Dhatu*, and involvement of *Mutravaha Strotas* (Urinary system), resulting in excessive and abnormal urination. It is characterised by profuse, turbid urination, reflecting systemic dysregulation of *Medovaha Strotas* and *Agnimandya* (diminished metabolic activity). All three *Doṣhas-Vata, Pitta*, and *Kapha*-are involved in its pathophysiology. Three basic therapeutic principles underpin Ayurved treatment of *Prameha*: *Shamana Chikitsa* (palliative or internal treatment), *Shodhana Chikitsa* (purification therapy), and *Nidana Parivarjana* (elimination or avoidance of causative factors). Within *Shamana Chikitsa*, classical scriptures describe several single and herbal compositions that help balance *Kapha*, rectify *Medo Dushti*, and restore *Agni*. One such formulation is *Salmusta* yoga, given by *Acharya Yogaratnakara* in the context of *Prameha Chikitsa* [3]. It comprises *Sal (Shorea robusta Gaertn. f.), Musta (Cyperus rotundus Linn.),* and *Kampillaka (Mallotus philippensis (Lam.) Mull. -Arg.).* It demonstrates *Kaphamedohara* (lipid-reducing), *Agnidipana* (metabolism-enhancing), and *Pramehaghna* (antidiabetic) properties. Thus, *Salmusta* yoga treats the core causes-*Agnimandya*, *Meda dushti*, and *Kapha Prakopa*-and restores metabolic balance through its combined phytotherapeutic effects [4-6]. Tablet metformin is a biguanide antihyperglycaemic agent and is considered the first-line drug for the management of diabetes mellitus [7].

REVIEW OF LITERATURE

Prameha is a disease *of Medovaha stotasa.* It is mentioned in *Brihattrayi* and in *Laghutrayi.* It is included in the *Ashtoumahagada by Acharya Charak. Hetu* (causes), *lakshana* (symptoms), and *samprapti* (pathogenesis) of *Prameha,* including *Madhumeha, are* described in *Sutrasthana* and *Nidanasthana* of *Charak Samhita.* The 20 types of *prameha*, involvement of *Dosha* and *Dushya* and treatment are described in *Chikitsasthana. Acharya Sushrut* explains *Madhumeha in Nidan sthana*, while its treatment is explained in *Chikitsa sthana.*

Raut NA et al., conducted an animal study to prove the antidiabetic activity of hydro ethanolic extract of *Cyperus rotundus* in alloxan-induced diabetes in rats. Oral daily administration of 500 mg/kg of the extract (once a day for seven consecutive days) significantly lowered blood glucose level. This antihyperglycaemic activity can be attributed to its antioxidant activity, as its strong DPPH radical scavenging action in-vitro [8].

Zhang W et al., conducted an in-vivo study to evaluate the hypoglycaemic effect of the methanolic extract of *Shorea roxburghii* leaves in rats with streptozotocin-induced T2DM, developed using a high-fat diet and fructose solution. The results demonstrated significant improvements, including lowered fasting blood glucose levels, reduced body weight, and decreased food and water intake in treated diabetic rats. These findings suggest the promising antidiabetic potential of *Shorea roxburghii* leaf extract and support its possible use in future management of T2DM [9].

The study conducted by Tanmane CS et al., on *Mustadikwath versus phalatrikadikwath* for diabetes mellitus type 2 demonstrated statistically significant improvements in clinical symptoms of *Madhumeha in both groups*, along with reductions in fasting blood glucose, postprandial blood glucose, and HbA1c levels over the treatment period [10].

Singh P et al., conducted animal study and found that the ethanolic extract (250 and 500 mg/kg body weight) of *Cyperus rotundus* showed a significant reduction in blood glucose levels, as well as reduction in the elevated level of SGPT, SGOT, serum cholesterol, and triglycerides with Body Mass Index (BMI) in STZ diabetic mice, comparable to that of standard drug glibenclamide at the 21st day of the study. Thus, the extract exhibited antidiabetic activity in STZ-induced diabetic mice, as evident from blood glucose levels [11].

Roy VK et al., conducted an animal study on the methanolic leaf extract of *M. roxburghianus* (MRME), which has shown a significant role of it in protecting animals from alloxan-induced diabetic oxidative stress in the pancreas and exhibited promising antihyperglycaemic and antioxidant activities along with significant reversal of disturbed antioxidant status and lipid peroxidative [12].

Similarly, Sumithira G et al., conducted an animal study to evaluate the antidiabetic activity of the *Mallotus philippensis.* They reported that alcoholic fruit extract of *Mallotus philippensis* decreased blood glucose, glycosylated haemoglobin and increased plasma insulin when administered orally for 21 days to STZ-induced diabetic rats with dose of 200 and 400 mg/kg. They demonstrated that rats treated with *Mallotus philippensis* alone showed a statistically significant antidiabetic effect compared to diabetic rats [13]. However, limited clinical evidence exists on *Salmusta* yoga efficiency, highlighting the need to evaluate its efficacy in managing *Madhumeha*.

Therefore, present study aims to evaluate and compare the efficacy of *Salmusta* yoga versus tablet metformin in the management of diabetes mellitus type 2 (*Madhumeha*).

Objectives

Primary objective:

- To evaluate the efficacy of *Salmusta* yoga on FBS and PPBS levels in T2DM.
- To evaluate the efficacy of tablet metformin on FBS and PPBS levels in T2DM.

Secondary objective:

- To compare the efficacy of *Salmusta* yoga and tablet metformin on FBS and PPBS levels in T2DM.

Null hypothesis (H_0): There is no significant difference in the efficacy of *Salmusta* yoga and tablet metformin in the management of T2DM (*Madhumeha*).

Alternative hypothesis (H_1): There is a significant difference in the efficacy of *Salmusta* yoga and tablet metformin in the management of T2DM (*Madhumeha*).

MATERIALS AND METHODS

A single-blind, parallel randomised controlled clinical trial will be conducted at the Mahatma Gandhi Ayurveda College Hospital and Research Centre, Salod (H), Wardha, Maharashtra, from September 2025 to June 2027. Before enrollment, written informed consent will be obtained from all participants after the nature, purpose, and procedures of the study are explained. Ethical approval for the trial has been granted by the Institutional Ethics Committee (IEC) vide approval number MGACHRC/IEC/July-2025/953. The trial has been registered with the Clinical Trials Registry of India (CTRI) under registration number CTRI/2025/08/093684.

Inclusion criteria:

- Patients are ready to give written consent;
- Age between-31 years- 60 years of either gender.
- Criteria for diagnosis of DM by the American Diabetes Association (ADA) [14].

FBS ≥126 mg/dL up to 375 mg/dL and/or

- PPBS ≥200 mg/dL up to 500 mg/dL
- Newly diagnosed cases.

Exclusion criteria:

Known cases of-

- IDDM-Insulin dependent diabetes mellitus and patients taking Insulin therapy;
- Patients having chronic diabetes problems like retinopathy, neuropathy and nephropathy;
- Patients with juvenile diabetes;
- Pregnant and lactating women.

Sample size calculation:

$n1=(\sigma1^2+\sigma2^2)\ (Z_{1-\alpha/2}+Z_{1-\beta})2/\Delta^2$

Δ =difference between the group means

κ ratio of n_2/n_1

$Z_{1-\alpha/2}$=two-sided Z value (e.g., Z=1.96 for a 95% confidence interval)

$Z_{1-\beta}$=statistical power.

Mean fasting blood glucose at day 75 in *Vidangadi* yoga Group=6.449 [15]

Mean fasting blood glucose at day 75 in metformin Group=7.820

$\sigma1$=SD of fasting blood glucose at day 75 in *Vidangadi* yoga Group=2.033

$\sigma2$=SD of fasting blood glucose at day 75 in metformin Group=1.678

For detecting mean difference of 1.370 i.e., Δ=7.820-6.449=1.370

K=1

$N=(2.033\times2.033+1.678\times1.678)\ (1.96+0.84)^2$

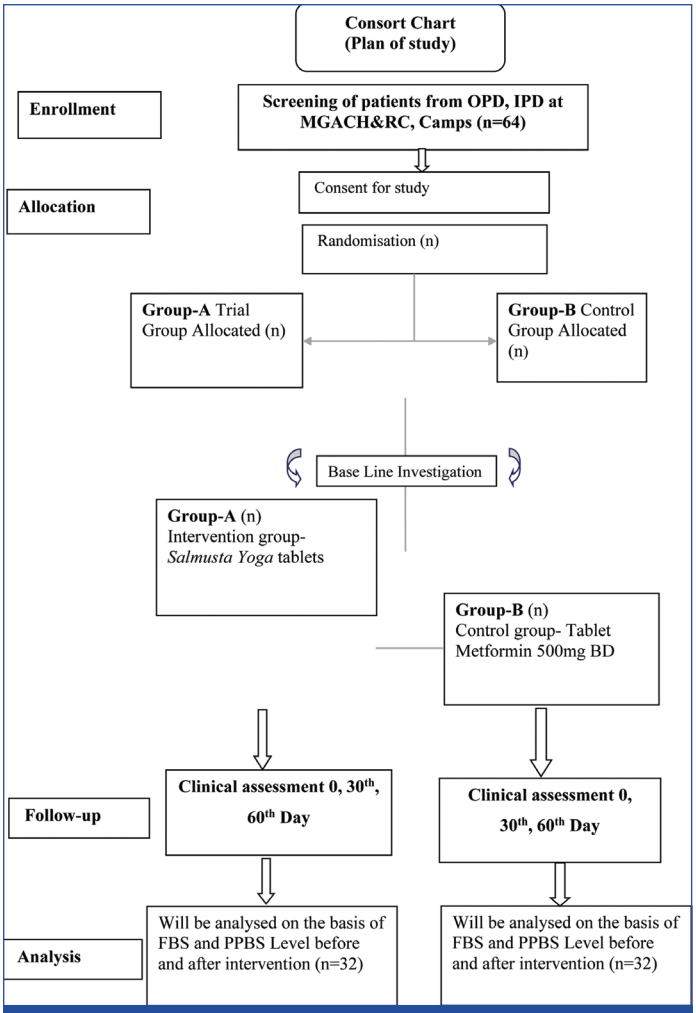
1.370×1.370

=28.98=29 patients needed in each group

Considering 10% dropout 29+3=32 in each group

A total sample size of 64 patients, comprising 32 patients in each group, will be selected using a simple randomisation technique employing a computerised random number table to ensure unbiased allocation and enhance internal validity [Table/Fig-1].

Randomisation 1:1 ratio using a computer-generated random number will be carried out by principal investigator. Block randomisation with variable block sizes will be applied to maintain group balance. Allocation concealment will be ensured by Sequentially Numbered, Opaque, Sealed, Envelopes (SNOSE). Group 1 will receive *Salmusta*



[Table/Fig-1]: Consolidated Standards of Reporting Trials (CONSORT) flow diagram.

yoga, while Group 2 will receive tablet metformin twice a day for two months [Table/Fig-2] [16,17].

Group	Sample size	Intervention	Dose and Frequency	Anupana	Duration	Follow-up
A (Trial)	32	*Salmusta* yoga	Crushed tablet 500 mg Twice a day [16,17]	*Madhu*	60 days	On 0, 30th and 60th day
B (Control)	32	Tablet metformin	500 mg BD	Water	60 days	

[Table/Fig-2]: Drug posology in Group A and Group B [16,17].

Withdrawal criteria: Patients who experience any negative effects or worsening of their symptoms will be excluded from the research.

Study Procedure

Preparation of the drug: Metformin 500 will be procured from a local pharmacy near Mahatma Gandhi Ayurveda College.

The raw drugs will be procured from the local authorised Ayurved market. The Department of *Dravyaguṇa*, Wardha, will be responsible for the proper identification and authentication of the crude drugs. The formulation *Salmusta* yoga will be prepared in the GMP-certified *Rasa Shala* (*Vedapoorna* Unit) of MGACH & RC, under the supervision and guidance of qualified subject matter experts in *Rasa Shastra* and *Dravyaguṇa*.

Authenticated raw materials

-Sala Tvak, Musta and Sodhita Kampillaka will be taken in equal proportions

↓

Each ingredient will be pulverised separately into fine powder (*Churṇa*)

↓

Powders will be mixed thoroughly to obtain a homogeneous blend

↓

Three sequential *Bhavanas* (triturations) will be done using fresh *Amla Swarasa (Emblica officinalis* juice) to enhance bioavailability and potency

↓

Granules (*Gola*) will be prepared from the *Bhavita Churṇa*

↓

Granules will be compressed to formulate *Vati* (tablets) following SOP from *Sharngadhara Samhita, Madhyama Khanda, Vati Kalpana Adhyaya.*

Outcomes

Primary outcomes: Reduction of Fasting Blood Sugar level (FBS);

Post Prandial Blood Sugar level (PPBS).

Secondary outcome: Comparison of both groups on FBS and PPBS;

Outcomes will be measured on days 0, 30, and 60 days.

Data management: The principal investigator will handle data coding.

Dissemination policy: Information will be disseminated through publication of articles, following established standards for authorship and appropriate use of professional writers. The Gantt chart of the present study is shown in [Table/Fig-3].

Scholar/ Investigator	Dr. Diksha Gaikwad					
Title	Evaluation of comparative efficacy of *Salmusta* yoga versus tablet metformin in the management of diabetes mellitus type 2 (*Madhumeha*)- A randomised controlled trial					
Steps	Q1 (September 2025)	Q2 (Dec 2025)	Q3 (April 2026)	Q4 (Aug 2026)	Q5 (Dec 2026)	Q6 (June 2027)
IEC authorisation						
Review of literature						
Preparation of drug						
Enrollment of patients						
Data collection						
Data analysis						
Thesis writing						
Thesis submission						

[Table/Fig-3]: Protocol's Gantt chart.

STATISTICAL ANALYSIS

Data will be analysed using Statistical Package for Social Sciences (SPSS) 27.0 software, and the Chi-square test, Student's unpaired and paired t-test, will be used for both descriptive and inferential statistical analysis. A significance level of $p<0.05$ will be considered.

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