

**CLINICAL STUDY TO COMPARE THE HYPOGLYCEMIC EFFECT OF
VIJAYSARGHANA VATI AND MAMAJJKAGHANA VATI IN MADHUMEHA~TYPE-2
DIABETES MELLITUS: PROTOCOL OF A CLINICAL COMPARATIVE STUDY**Kiran Chandolia^{*1}, Naimish Raj Singh²^{*1}PG Scholar, Dept. of Kayachikitsa, CBPACS, New Delhi, India.²Professor PG Dept. of Kayachikitsa, CBPACS, New Delhi, India.***Corresponding Author: Kiran Chandolia**

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ABSTRACT

Background: *Madhumeha* is a condition described in *Ayurveda* which has been correlated with Type-2 Diabetes Mellitus. It is one of the types of *Vataja Prameha*. Describing the *Prameha*, it has been mentioned it is group of disorders in which there is increased frequency of micturition, the volume of urine is also increased and the urine becomes turbid. According to *Acharya Charak*, *Madhumeha* is also called *Ojomeha*. **Aim and Objective:** To compare the efficacy of *Vijaysarghana Vati* and *Mamjjakaghana Vati* in *Madhumeha*~Type-2 Diabetes mellitus. **Material and Method:** This is a single-centre, open-label, randomized, comparative clinical study. Total 60 subjects in each group 30. Group A will receive *Vijaysarghana Vati* (500 mg, 2 tablets BD) and Group B will receive *Mamjjakaghana Vati* (500 mg, 2 tablets BD), both orally with plain water, empty stomach, 30 minutes before meals, for 90 days, followed by a 15-day follow-up. Outcomes will be assessed using fasting and postprandial blood glucose, HbA1c, and cardinal subjective symptoms of *Madhumeha*, recorded on Days 0, 1, 30, 60, 90 and at follow-up (Day 105). **Expected Outcome:** This study is expected to improvement in the biochemical parameters of Diabetes mellitus and clinical features of *Madhumeha* described in *Ayurvedic* texts.

KEYWORDS: *Ayurveda*, *Mamjjakaghana Vati*, Type-2 Diabetes Mellitus, *Vijaysarghana Vati*.**INTRODUCTION**

Madhumeha is a condition described in which has been correlated with Type-2 Diabetes Mellitus. It is one of the types of *Vataja Prameha*.^[1] The first people to notice that a patient's urine and blood tasted sweet when they had *Madhumeha* compared with DM were our *Ayurveda Acharyas*.^[2] Describing the *Prameha*, it has been mentioned it is group of disorders in which there is increased frequency of micturition, the volume of urine is also increased and the urine becomes turbid. Total types of *Prameha* are twenty in which *Ojomeha* (*Madhumeha*) is type of *Vataja Prameha*. All varieties of *Prameha* if neglected will, over a period of time, become *Madhumeha*. All those in which the urine is sweet resembling honey and the body also becomes sweet, hence all chronic *Pramehas* are called *Madhumeha*.^[3]

Depending on the etiology of DM, factors contributing to hyperglycemia include reduced insulin secretion,

decreased glucose utilization, and increased glucose production. In the United States, DM is the leading cause of End Stage Renal Diseases (ESRD), nontraumatic lower extremity amputations, and adult blindness. It also predisposes to cardiovascular diseases with an increasing worldwide, DM is likely to continue to be a leading cause of morbidity and mortality in the future.^[4]

PRESENT STATUS OF THE PROBLEM

Diabetes facts show the growing global burden for individuals, families, and countries. The latest International Diabetes Federation (IDF) Diabetes Atlas (2025) reports that 11.1% – or 1 in 9 – of the adult population (20-79 years) is living with Diabetes, with over 4 in 10 unaware that they have the condition.

Diabetes around the world in 2024 approximately 589 million adults (20-79 years) are living with diabetes. The total number of people living with diabetes is projected

to rise to 853 million by 2050. Over 4 in 5 adults (81%) with Diabetes live in low- and middle-income countries.^[5]

LACUNAE IN EXISTING KNOWLEDGE

Although, In modern medicine some of the most common medications to treat Diabetes Mellitus like Metformin, Sulfonylureas, Thiazolidinedione (TZDS), Alpha-glucosidase inhibitors, DPP-4 inhibitors, SGLT2 inhibitors, Bile acid sequestrants etc. In most of the cases, these medicines are required to be used for life long period which adds a large financial burden on the person. Further prolonged use of these drugs causes many adverse effect such as-gastrointestinal disturbances, loss of appetite, a metallic taste in mouth, anaemia, lactic acidosis, liver inflammation, jaundice, skin rashes with redness, flushing and itching, increase risk of Diabetes. Due to above reasons, there is need to search safer and more effective drug.

REASON FOR SELECTION OF VIJAYSARGHANA VATI AND MAMAJJAKGHANA VATI

Vijaysar (*Pterocarpus marsupium* Roxb.) and *Mamajjaka* (*Encicostemma littorale* Blume) are the herbal products which are easily available and are quite safe for longterm use. These herbal products have no side effects and cost effective. In *Ayurveda*, according to *Acharyas* these herbal products have been indicated in *Prameha*. It has also mentioned that *Vijaysar* and *Mamajjaka* are able to treat all types of *Prameha*. These medicinal plants having antidiabetic potential. As per Literature both these are mentioned to have hypoglycemic and antioxidant effects. Many research work had been carried out on *Vijaysar* and *Mamajjaka* but there is no comparative study that which one have more potency to lower blood sugar level.

RESEARCH QUESTION

Are *Vijaysarghana Vati* and *Mamajjakaghana Vati* equally effective in decreasing the level of Blood Sugar Fasting and Post Prandial in Madhumeha ~ T2 Diabetes mellitus?

HYPOTHESIS

NULL HYPOTHESIS (H₀)

There is no significant difference in hypoglycaemic effect of *Vijaysarghana Vati* and *Mamajjakaghana Vati* in the management of *Madhumeha*~T2 Diabetes mellitus.

Drug review

VIJAYSAR

Asana is a known plant widely available in all parts of India. References regarding the drug *Asana* is available in *Ayurveda* classics.

- *Charaka Samhita- Udardaprashaman Gana*
- *Susrutha Samhita -Salasaraadi Gana*
- *Astanga Sangraha- Asanadi Gana,*
- Shirovirechanopayogi*
- *Astanga Hrudaya- Asanadi Gana*
- *Priya Nighantu- Hareethakyadi Varga*
- *Shodhala Nighantu -Amradi Varga*
- *Bhavaprakasha Nighantu -Vatadi Varga*
- *Raj nighatu- Prabhadradi varga*

	Synonyms ^[6]	Botanical Classification ^[7]	Pharmacological Activity ^[8]	Properties ^[9]	Therapeutic Uses ^[10]
Vijaysar	<i>Asana, Bandhooka, Puspa, Beejaka, Beejariksha, Jeevaka, Kamyra, Karshya, Mahasarja, Alakapriya, Neelaka, Krishnasarjaka, Sarjaka, Shouri/Souri, Sugandhi, Syama, Thishya, Vijaysar.</i>	Botanical Name: <i>Pterocarpus marsupium</i> Roxb Kingdom - Plantae Family - Fabaceae Phylum- Magnoliophyta Genus- <i>Pterocarpus</i> Species- <i>Pterocarpus marsupium</i>	Anti-diabetic and antioxidant activity- <i>P. marsupium</i> demonstrates unique pharmacological properties, which include beta cell protective and regenerative properties as well as blood glucose lowering activity.	<i>Rasapanchaka Rasa - Kashaya, tikta Guna - Laghu rooksha Virya - Ushna Vipaka - Katu Doshaghanta - Kapha Pitta hara</i>	Dosage: 500 mg 2BD in the form of <i>Ghana Vati</i> Empty stomach (<i>Charaka Samhita, Sushruta Samhita, Ashtang Hridayam, Ashtang Sangraha</i>)

MAMAJJAKA

Mamajjaka (*Encicostemma littorale* Blume) has not been mentioned in the *Vedic* texts. There is no description in *Brihatrayi* and *Laghutrayi* either. The plant has first been described in *Shodhal Nighantu* in the 12th century.

Literature books

Shodhal Nighantu, Shaligram Nighantu, Bhawprakash Nighantu.

Antipyretic and anti-helminthic - Substitute of *Swertia Chirayata*.

	Synonyms	Botanical Classification ^[11]	Pharmacological Activity ^[12]	Properties (Shodhal Nighantu)	Therapeutic Uses ^[13]
Mamajjaka	<i>Mamajjaka, Nahi, Nagjivha, Tiktapatra, Kṛmihṛta, Kṣārakarma, Kṣitaukṣapa</i>	Latin name – Enicostemma littorale Blume Family- Gentianaceae English name - White head	It is the best medicine for the <i>Prameha</i> , especially in <i>Sthula Madhumeha</i> (Obese Diabetic), due to its <i>Tikta Rasa</i> and <i>Laghu, Ruksha Guna</i> . The Plant is bitter, Stimulant, Thermogenic, Digestive, Carminative, Stomachic, Laxative, Anti-helminthic, Anti-inflammatory, Liver tonic, urinary astringent, depurative, revulsive and anti-periodic.	<i>Rasa: Tikta</i> <i>Guna: Laghu, Ruksha</i> <i>Virya: Ushna</i> <i>Vipaka: Katu</i> <i>Karma: Kapha-Pitta Shamaka</i>	Indicated in <i>Vishama jwara, Atisara, Krimi, Madhumeha, Deepana, Amapachaka, Krimighna, Kushtaghna, Raktaprasadana.</i>

AIM AND OBJECTIVES

AIM

To compare the efficacy of *Vijaysarghana Vati* and *Mamjjakghana Vati* in *Madhumeha*~Type-2 Diabetes mellitus.

OBJECTIVES

PRIMARY OBJECTIVE: To compare the hypoglycaemic effect of *Vijaysarghana Vati* and *Mamjjakghana Vati* in *Madhumeha* ~Type 2 Diabetes mellitus.

SECONDARY OBJECTIVE: To compare the effectiveness of *Vijaysarghana Vati* and *Mamjjakghana Vati* in improving clinical features of *Madhumeha*~Type 2 Diabetes mellitus.

MATERIAL AND METHODS

Study design- Single centered, open label, interventional, comparative clinical study.

Study setting- OPD and IPD of Ch. Brahm Prakash Ayurved Charak Sansthan, Khera Dabar, New Delhi 110073 25 7.2

Inclusion criteria

1. Diagnosed patients of type-2 Diabetes mellitus.
2. Subjects with one or more Lakshana of Madhumeha.
3. Patients fulfilling the diagnostic criteria for type-2 diabetes mellitus by the AMERICAN DIABETES ASSOCIATION
4. Subjects not taking Insulin.
5. Subjects between age group-21 to 60 years.
6. Subjects of either sex.
7. The concomitant ongoing medicine with inclusion dose which may be permitted to the subject- 1. Metformin- 2000 mg in two divided doses (maximum dose)
2. Sulfonylureas- Glipizide 5mg to 40mg Glimepiride 1mg to 8mg
3. Vildagliptin 50 to 100 mg once or twice daily
4. Sitagliptin 50 to 100 mg once or twice daily

Exclusion criteria

1. Fasting blood sugar level <126mg/dl and >200mg/dl
2. Postprandial blood sugar level <200mg/dl and >350mg/dl
3. Patients below the age of 21years and more than age of 60years.
4. HbA1C<6.5% and > 10.0%
5. Pregnant ladies and lactating mothers.
6. Patients who already are registered in any other research projects.
7. Patients depending on the insulin for blood glucose control.
8. Patients with diabetic complications.
9. Patients suffering from secondary diabetes
10. Gestational diabetes

Withdrawal criteria

1. Patients developing any serious adverse effects.
2. Deteriorations of the condition of the patients after taking treatment.
3. Patients not willing to continue in study.
4. Patients who are not following the treatment regimen.

Diagnostic criteria

The American diabetes association (ADA) criteria for the diagnosis of diabetes:

Table no. 1: Diagnostic criteria.

Test	Diagnostic criteria for diabetes
HbA1c	≥ 6.5% indicates diabetes
Fasting plasma glucose (FPG)	≥ 126 mg/dL (7.0 mmol/L) suggests diabetes
Postprandial glucose (2hour OGTT)	≥ 200 mg/dL (11.1 mmol/L) indicates diabetes
Random plasma glucose	≥ 200 mg/dL (11.1 mmol/L) with symptoms suggests diabetes

SAMPLE SIZE

Total 60 will be selected into following two groups

(A) Trial Group- 30

(B) Comparator Group-30

SELECTION OF SUBJECT AND PROCEDURE

Sampling method- According to Inclusion and Exclusion criteria Subjects will be randomly selected from OPD and IPD of Ch. Brahm Prakash Ayurved Charak Sansthan, Khera Dabar, Najafgarh, New delhi-110073.

Drug source: The drug will be brought from Local market of Delhi and will be prepared by GMP Certified pharmacy.

Randomization Method: Randomization will be done by SNOSE Method (Sequentially Numbered, Opaque, Sealed Envelope)

DETAIL OF DRUG INTERVENTION**GROUP A (TRIAL GROUP)**

30 subjects will be given *Vijaysarghana Vati*

Dose and frequency: 500 mg Tablet 2BD, Empty stomach 30min before meal

Drug Administration: Orally

Anupana: With plain water

Duration of Intervention :90 days Follow up: after 15days

GROUP B (COMPARATOR GROUP)

30 subjects will be given *Mamajjakghana Vati*

Dose and frequency: 500mg Tablet 2BD, Empty stomach 30min before meal

Drug Administration: Orally

Anupana: With plain water

Duration: 90 days Follow up: after 15days

The Morisky Medication Adherence Scale (MMAS) a validated tool for assessing patient adherence to prescribed medications is incorporated wherever will be required.

Assessment criteria

Subjective assessment criteria: The assessment will be done with cardinal symptoms of Madhumeha 1.

Prabhuta-Mutrata

2. *Aavil- mutrata*

3. *Mutra -Madhurya*

4. *Atikshuda* (polyphagia), *Atitrishna* (polydipsia), *Daurbalya* (weakness), *Swapnasheela* (always desire to occupy bed), *Atisweda*, *Aasansheela*

Objective assessment criteria

Blood sugar level- • Fasting • Postprandial HbA1C

Patients will clinically assessed on day 0,1,30,60,90 days and findings would be noted in specified proforma and follow up of the subjects will be done after 15days intervention. The response of the patient's diseased condition will be observed and recorded before, during and after the treatment in a specially designed case proforma includes detailed history, physical examination, laboratory investigations and assessment based on subject and objective parameters for which appropriate scoring pattern is adopted.

PLAN OF STUDY: Table no.2.

Drug intervention	Day 0	Day 1	Day 30	Day 60	Day 90	Day 105 (follow up)
Screening	✓					
History taking with physical examination	✓					
Fasting blood sugar		✓	✓	✓	✓	✓

Post prandial blood sugar		✓	✓	✓	✓	✓
HbA1C		✓			✓	
Urine routine microscopic		✓				
Serum creatinine		✓				
Drug administration		✓				

GANTT CHART: Table no.3.

	July 2025	August 2025	September 2025	November 2025	December 2025	January 2026	February To November 2026	December To July 2027
							Tentative timeline	
Topic Finalization & synopsis writing	✓							
DRC	✓							
IRC		✓						
Synopsis submission after IRC changes			✓					
IEC				✓				
Synopsis submission after IEC changes					✓			
IRB					✓			
CTRI Registration						✓		
Patient Enrollment and Drug Intervention, follow up, Data collection,							✓	
Result generation Statistical Analysis, Thesis writing and Submission								✓

PRIMARY OUTCOME

Improvement in the biochemical parameters of Diabetes mellitus

- Fbs
- Ppbs
- HbA1C

SECONDARY OUTCOME

It includes clinical features of Madhumeha described in Ayurvedic texts.

These are

1. Prabhuta-Mutrata
2. Aavil mutrata
3. Mutra Madhurya
4. Atikshuda (polyphagia), Atitrishna (polydipsia), Daurbalya (weakness), Swapnasheela (always desire to occupy bed), Atisweda, Aasansheela

EFFECT SIZE

Effect size is calculated by using online effect size calculator

$$\text{Cohen's } d = (M2-M1)/SD$$

Where M1 mean of group 1 - 1.3

M2 mean of group 2 - 1.8

SD (standard deviation)

On the applying values on above formula

Effect size – 0.72

CRITERIA FOR TOTAL EFFECT OF THERAPY

For the assessment of the total therapy following four categories will be considered:

Cured- 76 TO 100% Complete relief in subjective sign and symptoms

Markedly improvement - 51 TO 75% Relief in subjective sign and symptoms

Improved -26 TO 50 % Relief in sign and symptoms

Unchanged- up to 25% Relief in some subjective sign and symptoms only.

STATISTICAL ANALYSIS

Data will be analysed at the end of the study period by using paired and unpaired t-test and paired t-test.

Criteria for the rejection or acceptance of Null Hypothesis

- Insignificant $p > 0.05$
- Significant $p < 0.05$

ETHICAL CONSIDERATION

All the ethical issues will be maintained during the clinical trial. Study will be carried out after obtaining ethical clearance from IEC.

SAFETY ASSESSMENTS

Adverse Event Reporting- Any unfavourable and unintended sign, symptom or disease that occurs during trial, whether or not it's considered causally related to the intervention will be identified, documented and reported to pharmacovigilance department.

DECLARATION

Study will be conducted within stipulated time.

Subjects will be registered in the study after getting registered in CTRI.

Conflict of interest – Nil.

The cost of the trial will be borne by the investigator.

Translational Value of the Research

This study seeks to elucidate the therapeutic potential of *Vijaysarghana vati* and *Mamajjakaghana vati* in Madhumeha~Type2 Diabetes mellitus, encompassing their clinical efficacy. It is expected that it will improve quality of life, lowering the blood sugar level (fasting and postprandial) and lowering the HbA1c level. Thus, this study would provide evidence-based research on action of the drug. If the study comes out to be successful, it will be very beneficial, non-invasive, easy to conduct, cost effective treatment and without any added side effects to the patients of Madhumeha~Type2 Diabetes mellitus.

Emergency Protocol and Compliance Responsibility

An emergency protocol will be in place throughout the duration of the trial to ensure participant safety and rapid response to any adverse events. In the event of unexpected medical complications, injury, severe discomfort, or adverse reactions related to the intervention, the session will be terminated immediately and the participant will receive prompt clinical assessment. Standard emergency procedures—including stabilization, first aid, and referral to appropriate medical institution—will be followed as per institutional guidelines. All adverse events, irrespective of severity, will be documented and reported to the principal investigator and the ethics committee as required. The Principal Investigator (PI) is responsible for enforcing adherence to the emergency protocol, overseeing participant safety, ensuring proper documentation, and coordinating with medical personnel when escalation of care is necessary. The PI will also ensure that all team members are trained in emergency procedures and that the protocol is implemented consistently across all study sessions.

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