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Protocol for an Open Labelled Randomised Comparative Clinical Study to Evaluate Efficacy of *Vangashilajatu* and *Nishaamalaki* in the Management of *Madhumeha* (T₂DM)

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Abstract: Background: *Madhumeha*, described in Ayurveda under *Vataja Prameha*, closely resembles Type 2 Diabetes Mellitus (T2DM), a chronic metabolic disorder characterized by persistent hyperglycaemia. Ayurveda advocates various therapeutic approaches including herbal formulations, dietary regulation, lifestyle modifications, and Yoga for its management. Although *Vangashilajatu* and *Nishaamalaki* are widely used in the treatment of *Madhumeha*, comparative clinical evidence regarding their efficacy remains limited.

Objective: To evaluate and compare the clinical efficacy and safety of *Vangashilajatu* and *Nishaamalaki* in the management of *Madhumeha* (T₂DM).

Methods and Design: This prospective, single-centre, open-labelled, randomized comparative clinical trial will include 60 patients aged 25–60 years diagnosed with *Madhumeha*. Eligible participants will be randomly allocated into two groups. Group A will receive *Vangashilajatu*, while Group B will receive *Nishaamalaki*. Both groups will receive appropriate *Pathya-Apathya* advice and treatment for 28 days. Clinical assessments will be performed on the 7th, 14th, 21st, and 28th day during treatment and on the 42nd and 56th day during post-treatment follow-up.

Expected Results: Primary outcomes will include changes in the cardinal signs and symptoms of *Madhumeha* described in Ayurvedic texts. Secondary outcomes will assess changes in fasting blood sugar, post-prandial blood sugar, HbA1c, and overall quality of life.

Conclusion: This study is expected to generate comparative clinical evidence regarding the efficacy of *Vangashilajatu* and *Nishaamalaki* in *Madhumeha*. Both formulations are anticipated to improve clinical symptoms and blood sugar parameters; however, *Vangashilajatu* is hypothesized to yield a superior efficacy and may serve as an effective Ayurvedic intervention for the management of *Madhumeha* (T₂DM).

I. INTRODUCTION

Madhumeha is one of the four types of *Vataja Prameha* (*Vasameha*, *Majjameha*, *Hastimeha* and *Madhumeha*) described in Ayurveda. ^[1] *Aavila Prabhotha Mutrata* ^[2] and *Prabhoota Aavila Mutrata* ^[3] are considered the cardinal features of *Prameha*. According to Ayurvedic principles, *Madhumeha* may develop either due to *Dhatukshaya* or as a consequence of *Avarana* caused by vitiated *Kapha* and *Meda*. In *Marga-Avaranajanya Madhumeha*, aggravated *Kapha* and *Meda* obstruct the normal movement of *Vata*, which subsequently carries *Ojas* towards the *Basti*, leading to the manifestation of *Madhumeha*. Due to the involvement of multiple *Doshas*, *Dushyas* and *Srotas*, *Madhumeha* is regarded as one of the most complex disorders described in Ayurvedic literature.

Madhumeha closely resembles Type 2 Diabetes Mellitus (T2DM), a heterogeneous metabolic disorder characterized by chronic hyperglycemia with disturbance of carbohydrate, fat and protein metabolism ^[4] resulting from defects in insulin secretion, insulin action, or both. Type 2 Diabetes Mellitus is strongly associated with sedentary lifestyle, unhealthy dietary habits, obesity and genetic predisposition ^[5]

The disease has emerged as a major public health challenge due to its increasing prevalence and associated complications. In Haryana, the prevalence of diabetes has been reported to be 15.1%, emphasizing the growing regional burden of the disease^[6] According to the International Diabetes Federation (IDF), approximately 537 million adults were living with diabetes in 2021 and this number is projected to increase to 783 million by 2045^[7] The World Health Organization reported that diabetes affects 422 million people globally and remains a significant contributor to morbidity and mortality.^[8]

Ayurveda offers several therapeutic modalities for the management of *Madhumeha*. *Vangashilajatu*, a formulation comprising *Shuddha Shilajatu* and *Vanga Bhasma*, and *Nishaamalaki*, a classical formulation containing *Haridra* and *Amalaki*, are commonly used in the management of *Madhumeha*. Several studies have evaluated the efficacy of *Vanga*-based formulations, *Shilajatu* preparations and *Nishaamalaki* individually. However, no comparative clinical study evaluating the efficacy of *Vangashilajatu* and *Nishaamalaki* has been reported. Therefore, the present study was undertaken to compare the clinical efficacy of *Vangashilajatu* and *Nishaamalaki* in the management of *Madhumeha* with special reference to Type 2 Diabetes Mellitus and to generate evidence for their potential integration into contemporary diabetes care.

II. MATERIALS AND METHODS

A. Study Design

An open-label, randomized, parallel-group comparative clinical study will be conducted to evaluate the efficacy of *Vangashilajatu* and *Nishaamalaki* in the management of *Madhumeha* with special reference to Type 2 Diabetes Mellitus.

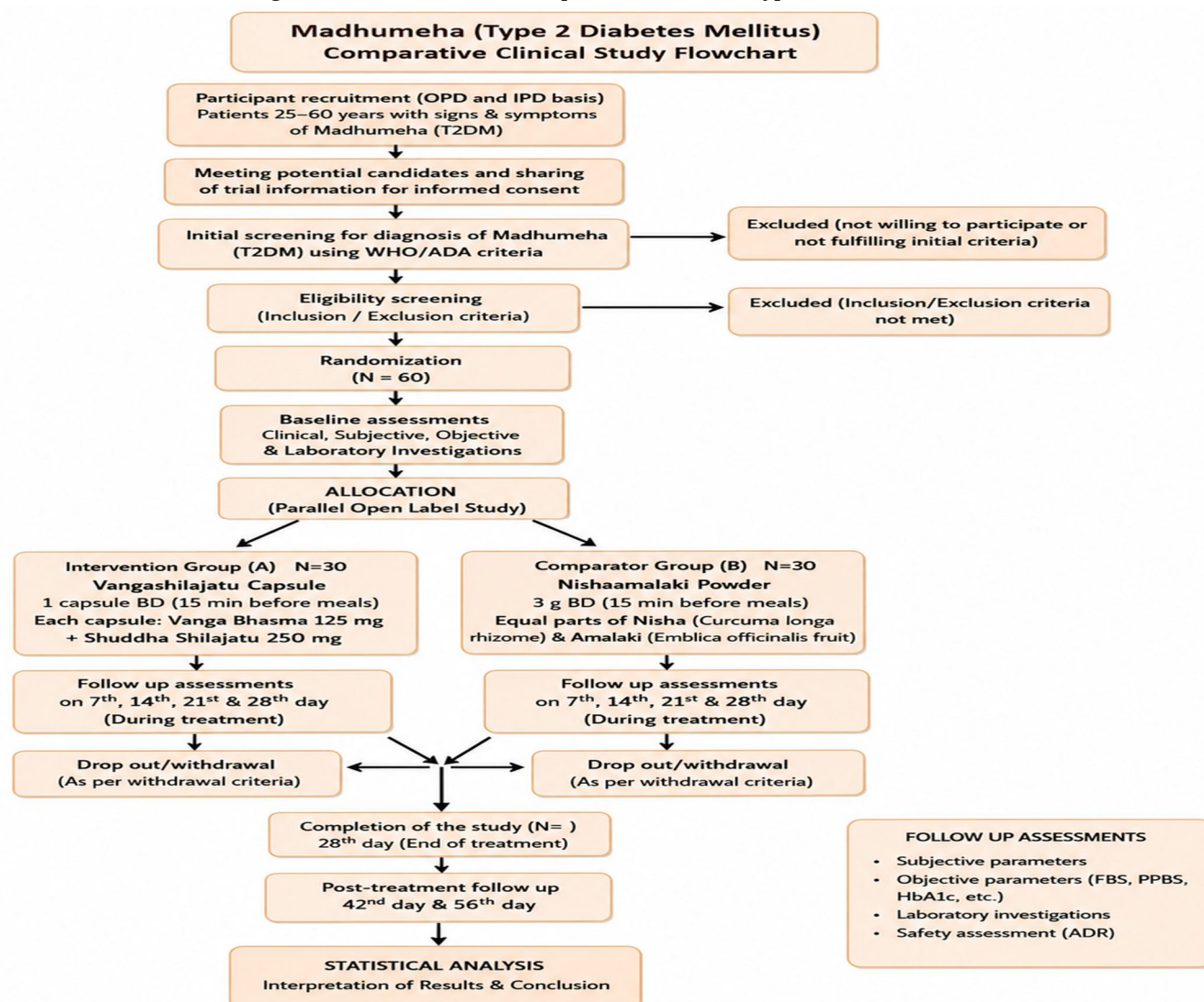


Fig. 1: Trial Design

B. Participants

The study will be conducted in the Outpatient Department (OPD) and Inpatient Department (IPD) of the P.G. Department of Kayachikitsa, Institute for Ayurved Studies and Research, Faculty of Ayurved, Shri Krishna AYUSH University, Kurukshetra, Haryana.

C. Sample Size and Randomization

A total of 60 patients diagnosed with *Madhumeha* (Type 2 Diabetes Mellitus) will be selected and randomly allocated into two groups consisting of 30 patients each using a computer-generated randomization schedule.

- Group A (n = 30): *Vangashilajatu*
- Group B (n = 30): *Nishaamalaki*

D. Selection Criteria

1) Inclusion Criteria

- Patients willing to provide written informed consent.
- Patients of either sex aged between 25 and 60 years.
- Patients fulfilling the diagnostic criteria of Type 2 Diabetes Mellitus.
- Fasting Blood Sugar (FBS) between 126–200 mg/dL.
- Post-Prandial Blood Sugar (PPBS) between 200–300 mg/dL.
- HbA1c between 6.5% and 8%.
- Patients presenting with classical signs and symptoms of *Madhumeha* described in Ayurvedic texts.

2) Exclusion Criteria

- Patients unwilling to participate in the study.
- Patients below 25 years or above 60 years of age.
- Type 1 Diabetes Mellitus, Gestational Diabetes Mellitus, MODY, and LADA.
- Diabetes secondary to endocrinopathies.
- Patients with severe diabetic complications.
- Pregnant and lactating women.
- Patients suffering from severe hepatic, renal, cardiovascular, or malignant disorders.

3) Withdrawal criteria

- Patients developing any serious side effects.
- Deteriorations of the condition of the patient after taking treatment.
- Patients not willing to continue in the study.

E. Ethical Clearance

The study protocol was approved by the Institutional Ethics Committee of Shri Krishna AYUSH University, Kurukshetra. The study was registered with the Clinical Trials Registry–India (CTRI). Written informed consent was obtained from all participants before enrollment.

Ethical Approval No.: SKAU/Acad/2024/10802

CTRI Registration No.: CTRI/2024/07/071147

F. Interventions

Group A – *Vangashilajatu* ^[9]

Patients will receive one capsule of *Vangashilajatu* twice daily, 15 minutes before meals with water for 28 days. Each capsule contained:

Table no: 1- Contents of Vangashilajatu

S.no	Drug	Scientific name	Rasa	Guna	Virya	Vipaka
1.	Vang Bhasma	Tin (Stannum)	Tikta, Kashaya, Slight Lavana	Ruksha, Laghu	Ushna	Katu Vipaka
2.	ShuddhaShilajitu	Asphaltum Punjabianum	Kashaya and Slight Amla Rasa	Ruksha	Slight Sheeta, slight Ushna	Katu Vipaka

- Vanga Bhasma – 125 mg. ^[10]
- Shuddha Shilajatu – 250 mg. ^[11]

Group B – Nishaamalaki ^[12]

Patients will receive *Nishaamalaki Churna* 3 g twice daily, 15 minutes before meals with water for 28 days. The formulation consisted of equal proportions of *Nisha (Curcuma longa)* and *Amalaki (Emblica officinalis)* prepared according to *Ashtanga Hridaya*.

Table no: 2 - Contents of Nishaamalaki

S.no	Drug	Scientific Name	Part Used	Rasa	Guna	Virya	Vipaka
1.	Nisha	Curcuma longa	Rhizome	Tikta-Katu	Ruksha – Laghu	Ushana	Katu
2.	Amalaki	Emblica officinalis	Fruit	Pancharasa	Guru, Ruksha, sheeta	Sheeta	Madhura

G. Study Procedure and Follow-up

Written informed consent Will be obtained from all participants before enrollment. A detailed medical history will be recorded and a comprehensive physical examination will be performed at baseline. Clinical assessment will be carried out using predefined subjective and objective parameters before initiation of treatment and during subsequent follow-up visits. Baseline laboratory investigations will be performed to confirm the diagnosis, assess disease severity, and ensure participant eligibility. Patients fulfilling all inclusion criteria and none of the exclusion criteria will be enrolled in the study. Following enrollment at baseline (Day 0; Visit 1), participants will be evaluated weekly during the treatment period on Day 7 (Visit 2), Day 14 (Visit 3), Day 21 (Visit 4), and Day 28 (Visit 5). Post-treatment follow-up assessments will be conducted on Day 42 (Visit 6) and Day 56 (Visit 7).

At each visit, vital signs, physical examination findings, clinical symptoms of *Madhumeha*, treatment compliance, and adverse events will be recorded. Laboratory investigations including Fasting Blood Sugar (FBS), Post-Prandial Blood Sugar (PPBS), and HbA1c will be performed according to the study schedule. Participants will free to withdraw from the study at any stage without providing a reason and without affecting their routine medical care.

H. Assessment criteria

1) Subjective Criteria ^{[13][14][15][16]}

The following clinical findings will be assessed before, during and after treatment. According to WHO Assessment Scale of Clinical Features on the basis of classical ayurvedic text:

AAVILA MUTRATA (TURBIDITY)

1.	Crystal clear fluid	0
2.	Faintly cloudy, smoky, or hazy with slight turbidity.	1
3.	Turbidity clearly visible but new sprint easily read through test tube	2
4.	New sprint not easily read through test tube	3
5.	New sprint cannot be seen through test tube	4

MUTRA MADHURYA (GLYCOSURIA)

1.	Absence of Glucose in urine	0
2.	Traces of Glucose in urine	1
3.	+ Glucose in urine	2
4.	+ + Glucose in urine	3
5.	+ + + Glucose in urine	4
6.	+ + + + Glucose in urine	5

PIPASA –ADHIKYA (INCREASED THIRST)

1.	Feeling of thirst (7–9times/24hours) & relieved by drinking water	0
2.	Feeling of moderate thirst (>9-11 times/24hours) & relieved by drinking water	1
3.	Feeling of excess thirst (>11–13 times/24hours) not relieved by drinking water	2
4.	Feeling of severe thirst (>13times) not relieved by drinking water.	3

KSHUDHA-ADHIKYA (INCREASED APPETITE) : (1 MEAL = ABOUT 350 GM DIET)

1.	As usual/ routine	0
2.	Slightly increased (meal extra with routine diet)	1
3.	Moderately increased(2 meals extra with routine diet)	2
4.	Markedly increased (3 meals extra with routine diet)	3

SWED ADHIKYA (PERSPIRATION)

1.	Sweating after heavy work and fast movement or in hot weather	0
2.	Profuse sweating after moderate work and movement	1
3.	Sweating after little work and movement (stepping ladder etc.)	2
4.	Profuse sweating after little work and movement	3
5.	Sweating even at rest or in cold weather	4

ANGA GANDHA (BAD ODOUR)

1.	No odour	0
2.	Bad odour but not offensive	1
3.	Strong odour but can be lessened by the use of deodorants or perfumes	2
4.	Very strong odour even after using fragrances (use of deodorants or perfumes)	3

NIDRA ADHIKYA (INCREASED SLEEP)

1.	Normal & sound sleep for 6 – 8 hrs. /24 hrs. with a feeling of lightness and relaxation in the body & mind	0
2.	Sleep>8-9hrs./24hrs. with slight heaviness in the body.	1
3.	Sleep>9-10hrs./24hrs. with heaviness in the body associated with <i>Jrimbha</i> .	2
4.	Sleep>10hrs./24hrs. with heaviness in the body associated with <i>Jrimbha</i> & <i>Tandra</i>	3

HASTA-PADA-TALA DAHA

1.	No <i>Daha</i>	0
2.	<i>Hasta-Pada-Tala Daha</i> found occasionally, mild, bearable	1
3.	<i>Hasta-Pada-Tala Daha</i> is continuous but bearable & not severe	2
4.	<i>Hasta-Pada-Tala-Daha</i> continuous and severe & unbearable	3

KARA-PADA SUPTATA

1.	No suptata	0
2.	Kara-Pada Suptata in continuous	1
3.	Kara-Pada Suptata continuous but bearable & not severe	2
4.	Kara-Pada Suptata is continuous and severe & unbearable	3

PRABHUTA MUTRATA (POLYURIA): FREQUENCY OF URINE

1.	3-5 times per day, not rarely at night	0
2.	6-8 times per day, 1 - 2 times per night	1
3.	9-11 times per day, 3 - 4 times per night	2
4.	>11 times per day, > 4 times per night	3

2) Objective Criteria

Reduction in FBS Value

0%	Grade 0
1-24%	Grade 1
25-49%	Grade 2
50-74%	Grade 3
75-99%	Grade 4
100%	Grade 5

Reduction in PPBS Value

0%	Grade 0
1-24%	Grade 1
25-49%	Grade 2
50-74%	Grade 3
75-99%	Grade 4
100%	Grade 5

Reduction in HbA1C Value

0%	Grade 0
1-24%	Grade 1
25-49%	Grade 2
50-74%	Grade 3
75-99%	Grade 4
100%	Grade 5

3) Laboratory Investigations

Following investigations will be done for safety of the drugs and to exclude the cases as per the exclusion criteria mentioned earlier.

S. No.	Parameters	Before treatment	During treatment				Post treatment follow up	
		0th Day	7th Day	14th Day	21st Day	28th Day	42nd Day	56th Day
1.	Hb	✓						
2.	TLC	✓						
3.	DLC	✓						
4.	ESR	✓						
5.	Fasting Blood Sugar	✓	✓	✓	✓	✓	✓	✓
6.	PP Blood Sugar	✓	✓	✓	✓	✓	✓	✓
7.	HbA1C	✓				✓		
8.	Blood Urea	✓		✓		✓		
9.	Serum Creatinine	✓		✓		✓		
10.	Serum Cholesterol	✓						
11.	Serum Triglyceride	✓						
12.	SGOT	✓						
13.	SGPT	✓						
14.	Alkaline Phosphatase	✓						
15.	Urine (R&M)	✓				✓		

III. OUTCOME MEASURES

- 1) Subjective: Clinical symptom scoring (pallor, anorexia, weakness, dyspnea, etc.) using standard Ayurvedic scales.
- 2) Objective: Laboratory tests including Hemoglobin, serum ferritin.

IV. ANALYSIS

Data will be summarized as mean $\pm$ SD. Intergroup comparisons will utilize independent t-tests (or nonparametric equivalents), and within-group changes will be analyzed by paired t-tests. Statistical significance will be set at $p < 0.05$ using standard statistical software.

V. DISCUSSION

This protocol addresses an important gap in Ayurvedic research by comparing the efficacy of *Vangashilajatu* and *Nishaamalaki* in the management of *Madhumeha*. *Vangashilajatu* comprises *Shuddha Shilajatu* and *Vanga Bhasma*. *Vanga Bhasma* possesses *Tikta*, *Kashaya* and *Alpa Lavana Rasa* along with *Laghu* and *Ruksha Guna*, which may help in alleviating *Kapha* and *Meda Dushti*, the principal pathological factors involved in *Madhumeha*.^[17] *Shuddha Shilajatu* possesses *Anamla* and *Kashaya Rasa*, *Ushna-Sheeta Veerya* and *Katu Vipaka*, which together may help in correcting *Kapha Dushti* and *Meda* vitiation associated with *Madhumeha*.^[18] *Nishaamalaki* has been mentioned in *Ashtanga Hridya* for the management of *Madhumeha* and has also been included in the AYUSH Essential Drug List 2022. Previous studies have demonstrated its efficacy in the treatment of *Madhumeha*. According to Ayurveda, *Prameha* occurs due to the vitiation of all three *Doshas*, with *Kapha* and *Meda* playing a predominant role in its pathogenesis.^[19] Sedentary lifestyle, lack of exercise and excessive intake of *Kapha*-promoting foods are considered important *Nidanas* for the disease.^[20] All factors increasing *Kapha*, *Mutra* and *Meda* are regarded as major causative factors of *Prameha*.^[21] In classical writings, *Madhumeha* is referred to as *Mahatyaya* which is a synonym for *Mahavyapattikara* (creating serious troubles).^[22]

Diabetes Mellitus is a metabolic disorder characterized by chronic hyperglycemia due to defects in insulin secretion, insulin action, or both.^[23] Type 2 Diabetes Mellitus is characterized by insulin resistance with progressive β -cell dysfunction and relative or absolute insulin deficiency.^[24]

Previous research has evaluated *Vanga Bhasma* and *Shuddha Shilajatu* individually in *Madhumeha*, but a comparative evaluation of *Vangashilajatu* and *Nishaamalaki* has not been conducted. Therefore, there is a need to study the comparative effect of these commonly used Ayurvedic formulations to address this research lacuna. By integrating classical Ayurvedic principles with modern clinical evaluation techniques, this study strives to validate the potential benefits, safety and cost-effectiveness of *Vangashilajatu* in comparison with *Nishaamalaki* in the management of *Madhumeha*. The open-label design is balanced by rigorous, objective outcome assessments which are expected to yield reproducible and clinically relevant data that could inform future large-scale trials.

VI. CONCLUSION

This study protocol details an open labelled, parallel comparative clinical trial aimed at evaluating the efficacy and safety of *Vangashilajatu* versus *Nishaamalaki* in patients with *Madhumeha* (TYPE 2 DM). Successful results could pave the way for evidence based integration of Ayurvedic treatment modalities into modern healthcare practice.

A. Funding Sources

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B. Conflict of Interest

The authors declare no conflict of interest.

C. Declaration of generative AI in scientific writing

The authors have not used any AI tools for writing this manuscript.

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