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# Comparing the effect of two Ayurveda drugs on the treatment of type 2 diabetes mellitus

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| **Submission date**<br>17/09/2025 | **Recruitment status**<br>Recruiting | [X] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[_] Results<br>[_] Individual participant data<br>[X] Record updated in last year |
| **Registration date**<br>05/10/2025 | **Overall study status**<br>Ongoing | |
| **Last Edited**<br>17/11/2025 | **Condition category**<br>Nutritional, Metabolic, Endocrine | |

**Plain English summary of protocol**

Background and study aims

Type 2 diabetes mellitus (T2DM) is a long-term condition in which the body does not use insulin properly, leading to raised blood glucose levels. Over time, poor control of blood sugar can cause serious complications such as heart disease, kidney damage, nerve damage, and eye disease. Current treatments, including oral drugs like metformin, are effective but may cause side effects and long-term use can reduce patient compliance. Gymnema sylvestre (locally known as Masbedda) is a medicinal plant widely used in Ayurveda for the management of diabetes, with reports of blood sugar–lowering effects. The aim of this study is to find out whether Gymnema sylvestre (given as either a decoction or a freeze-dried powder) is as effective and safe as standard metformin treatment in controlling diabetes over a period of 12 weeks.

Who can participate?

Men and women aged 18 to 65 years who have been diagnosed with type 2 diabetes mellitus.

What does the study involve?

Participants will be randomly assigned to one of three groups:
-Gymnema sylvestre decoction (prepared fresh daily from coarse leaf powder)
-Gymnema sylvestre freeze-dried powder (sachets dissolved in hot water)
-Standard treatment with metformin (500 mg, twice daily)
The study treatment will continue for 12 weeks. At the start, all participants will undergo full clinical and laboratory tests. Blood sugar (fasting glucose) will be checked every two weeks using a glucometer for safety monitoring, with an additional laboratory test at week six. At the end of 12 weeks, a full set of investigations will be repeated. The main outcome is change in HbA1c (a marker of long-term blood sugar control) between baseline and the end of treatment.

What are the possible benefits and risks of participating?

Participants will receive close monitoring and advice from a qualified medical team. They may benefit from improved blood sugar control and contribute to the development of an evidence-based Ayurveda treatment option for diabetes. The risks are expected to be minimal and mainly include gastrointestinal side effects sometimes seen with diabetes treatments.

Where is the study run from?
Faculty of Indigenous Medicine, University of Colombo, Sri Lanka.

When is the study starting and how long is it expected to run for?
July 2025 to December 2026

Who is funding the study?
Faculty of Graduate Studies, University of Colombo, Sri Lanka.

Who is the main contact?
Dr Erandi Gunathilaka, 2024mphilphd08@stu.cmb.ac.lk

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# Additional identifiers

**Clinical Trials Information System (CTIS)**
Nil known

**ClinicalTrials.gov (NCT)**
Nil known

**Protocol serial number**
2024/MPhil-PhD/08

# Study information

**Scientific Title**
Gymnema sylvestre in the management of type 2 diabetes mellitus: a three-arm, open-label, non-inferiority randomised controlled trial

**Acronym**
AyurDrugT2DM

## Study objectives
Objective of this study is to compare the efficacy of GS Panta Kashaya and freeze-dried GS formula with metformin in reducing HbA1c levels in patients with T2DM over 12 weeks.

## Ethics approval required
Ethics approval required

## Ethics approval(s)
approved 22/07/2025, Ethics Review Committee, Faculty of Indigenous Medicine (University of Colombo, Sri Lanka, Colombo, -, Sri Lanka; +94 112692385; ethicsreview@fim.cmb.ac.lk), ref: ERC 25/272

## Study design
Three-arm open-label non-inferiority randomized controlled clinical trial

## Primary study design
Interventional

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Type 2 diabetes mellitus

## Interventions
This will be a three-arm, open-label, non-inferiority randomized controlled trial in patients with type 2 diabetes mellitus (T2DM). Participants will be recruited using a consecutive consenting sampling method. A blocked randomization design will be applied, with the randomization schedule generated through an online statistical computing tool. Eligible participants will be randomly assigned to one of three arms.
Arm I will receive GS decoction prepared from 5 g of pre-packaged coarse leaf powder boiled in 60 ml of water and taken once daily after meals; Arm II will receive freeze-dried GS powder equivalent to the decoction, packaged in sachets and dissolved in 60 ml of hot water as a single daily dose; Arm III will receive metformin 500 mg orally twice daily after meals with 240 ml of water. The intervention period will last 12 weeks, followed by post-treatment assessments at 1 and 3 months without further drug administration
All participants will attend clinic visits every two weeks during the intervention period.
The primary outcome is change in glycated hemoglobin (HbA1c) from baseline to week 12. Considering that HbA1c reflects glycemic control over 8–12 weeks, intermediate testing will not provide clinically meaningful data. Therefore, secondary outcomes will be assessed on a structured schedule: baseline (comprehensive investigations), biweekly capillary fasting blood sugar (FBS) monitoring using a glucometer for safety and trends, an additional laboratory FBS measurement at week 6, and full investigations again at week 12. Secondary outcomes include FBS, insulin sensitivity (HOMA-IR), body weight, BMI, gastrointestinal side effects, liver enzymes (ALT, AST), serum creatinine, and estimated glomerular filtration rate (eGFR). Data will be entered and cleaned in SPSS, with outlier management and necessary transformations applied. Descriptive statistics will summarize baseline and outcome measures, while inferential analysis will be performed using t-tests or ANCOVA (adjusted for baseline), with chi-square or non-parametric tests applied to categorical outcomes. Subgroup analyses will be conducted if relevant.

### Intervention Type
Drug

### Phase
Phase II

### Drug/device/biological/vaccine name(s)
Gymnema Sylvestre shade dried leaf powder, Gymnema Sylvestre freeze dried powder, metformin

### Primary outcome(s)
Change in HbA1c levels measured by venous blood test at baseline and 12 weeks.

### Key secondary outcome(s))
1. Change in fasting blood glucose levels measured by venous blood test at baseline and 12 weeks, and random blood sugar (RBS) every two weeks using a glucometer strip test.
2. Change in insulin sensitivity (HOMA-IR) calculated from fasting glucose and fasting insulin levels at baseline and 12 weeks.
3. Incidence and severity of gastrointestinal side effects assessed using patient interviews and symptom questionnaires at each follow-up visit (baseline, 4 weeks, 8 weeks, and 12 weeks).
4. Change in body weight and BMI measured using a calibrated scale and stadiometer at baseline and 12 weeks.
5. Change in liver enzyme levels (ALT, AST) at baseline and 12 weeks.
6. Serum creatinine levels at baseline and 12 weeks.
7. Estimated glomerular filtration rate (eGFR) calculated from serum creatinine at baseline and 12 weeks.

### Completion date
30/12/2026

## Eligibility

### Key inclusion criteria
1. Age 18-70 years.
2. Diagnosed with T2DM for at least 6 months, confirmed by medical records and HbA1c levels.
3. HbA1c levels between 7.0% and 9.5% at screening, despite receiving stable doses of metformin or no metformin therapy for at least 3 months.
4. Willing and able to provide written informed consent.

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Mixed

### Lower age limit
18 years

### Upper age limit
70 years

### Sex
All

### Total final enrolment
0

### Key exclusion criteria
1. Type 1 Diabetes Mellitus or other specific types of diabetes.
2. History of severe hypoglycaemia requiring hospitalization in the past 6 months.
3. Pregnant or breastfeeding women.
4. Active liver disease (defined as AST or ALT > 3 times the upper limit of normal).
5. Estimated glomerular filtration rate (eGFR) < 30 ml/min/1.73 $m^2$.
6. Known allergy or intolerance to GS or metformin.
7. Currently using any other investigational drugs or herbal supplements for diabetes management.

### Date of first enrolment
27/12/2025

### Date of final enrolment
01/12/2026

## Locations

### Countries of recruitment
Sri Lanka

### Study participating centre
**National Ayurveda Teaching Hospital**
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-

## Sponsor information

### Organisation
University of Colombo

### ROR
https://ror.org/02phn5242

# Funder(s)

### Funder type
University/education

### Funder Name
University of Colombo

### Alternative Name(s)
University of Colombo, Sri Lanka, UoC

### Funding Body Type
Government organisation

### Funding Body Subtype
Local government

### Location
Sri Lanka

# Results and Publications

### Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Erandi Gunathilaka (2024mphilphd08@stu.cmb.ac.lk). Study participant data sheets will not include contact or identifying details. Study data entry and study management systems used by clinical sites will be secured and password protected. At the end of the study, all study databases will be de-identified and archived. Availability of raw data of the study is based on the above conditions.

### IPD sharing plan summary
Available on request

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Other files | Demographics | | 22/09/2025 | No | No |
| Other files | Gastrointestinal Symptom Questionnaire | | 22/09/2025 | No | No |
| Other files | Medical History Questionnaire | | 22/09/2025 | No | No |
| Other files | Medication Adherence Questionnaire | | 22/09/2025 | No | No |
| Participant information sheet | | | 22/09/2025 | No | Yes |

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|---|---|---|---|---|---|
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |