

Evaluation of glycemic control in type 2 diabetes patients using Diafree juice

Submission date 03/07/2025	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 29/07/2025	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 25/07/2025	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

This study aims to assess how effective a herbal product called Diafree Juice is in helping people with type 2 diabetes manage their blood sugar levels. Diafree Juice is an Ayurvedic formulation already being used by patients as part of their regular diabetes care. The study analyzes anonymized health data shared by physicians to understand if Diafree Juice leads to improvements in two key measures of blood sugar: HbA1c and post-meal glucose levels.

Who can participate?

People diagnosed with type 2 diabetes, aged 18 years or older, with HbA1c values between 5.5% and 7% who have already been prescribed Diafree Juice by their doctor as part of routine treatment.

What does the study involve?

There is no direct involvement from patients. Doctors who are already treating these individuals shared anonymized health records, including blood sugar levels before and after the use of Diafree Juice. The study does not require any new medication, lab tests, or visits.

What are the possible benefits and risks of participating?

There are no direct risks or benefits to the patients included in this study. Since the study only uses anonymized data that was already collected as part of routine care, there is no additional burden or intervention for patients. The results of this study may help inform future research and improve clinical understanding of the product's role in diabetes management.

Where is the study run from?

The study is coordinated by the Kapiva Academy of Ayurveda in Bengaluru, India, using data collected from Ayurvedic doctors across the country.

When is the study starting and how long is it expected to run for?

April 2024 to December 2024

Who is funding the study?

The study is funded and sponsored by Adret Retail Private Limited (Kapiva Ayurveda), based in Bengaluru, India.

Who is the main contact?

Dr Anushri Shah, anushri.shah@kapiva.in

Contact information

Type(s)

Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

KAA/RD/PMS-DF/2024/001

Study information

Scientific Title

Evaluating the effect of Diafree Juice on blood sugar control in type 2 diabetes: a retrospective study

Study objectives

Diafree Juice reduces HbA1c and postprandial plasma glucose (PPBG) in patients with type 2 diabetes mellitus over a 12-week period.

Ethics approval required

Ethics approval not required

Ethics approval(s)

Study design

Open-label prospective single-arm observational

Primary study design

Observational

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Type 2 Diabetes Mellitus

Interventions

Participants included in this study were individuals with type 2 diabetes who had already been prescribed Diafree Juice by their treating physicians as part of routine care. The study did not involve any new intervention, enrolment, or patient contact. Physicians shared anonymized clinical data for eligible patients, including HbA1c and postprandial plasma glucose (PPBG) levels at baseline (prior to Diafree Juice initiation) and after approximately 12 weeks (84 days) of continued product use. No additional follow-up or study procedures were required beyond standard medical care. The total duration of observation per patient was 12 weeks.

Intervention Type

Other

Primary outcome(s)

HbA1c level measured using laboratory test results reviewed from patient medical records maintained by treating physicians at Baseline (prior to Diafree Juice initiation) and after 12 weeks (Day 84)

Key secondary outcome(s)

Postprandial Plasma Glucose (PPBG) (mg/dL) measured using laboratory test results reviewed from patient medical records maintained by treating physicians at Baseline (prior to Diafree Juice initiation) and after 12 weeks (Day 84)

Completion date

31/12/2024

Eligibility

Key inclusion criteria

Diagnosed T2DM with HbA1c 5.5–7%

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Total final enrolment

82

Key exclusion criteria

1. Type 1 DM, insulin therapy
2. Fluctuating OHA doses
3. Contraindication to herbal use

Date of first enrolment

15/04/2024

Date of final enrolment

27/12/2024

Locations

Countries of recruitment

India

Study participating centre

Kapiva Academy of Ayurveda

India

560103

Sponsor information

Organisation

ADRET RETAIL PRIVATE LIMITED (KAPIVA)

Funder(s)

Funder type

Industry

Funder Name

ADRET RETAIL PRIVATE LIMITED (KAPIVA)

Results and Publications

Individual participant data (IPD) sharing plan

Participant-level data will not be shared due to confidentiality and data protection policy. Only aggregate results will be disseminated.

IPD sharing plan summary

Not expected to be made available