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

Submission date 03/07/2025	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 29/07/2025	**Overall study status** Completed	
Last Edited 25/07/2025	**Condition category** Nutritional, Metabolic, Endocrine	

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

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