Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Effects of Mangifera indica extract supplement on metabolic status in type 2 diabetic patients

Protocol summary

Study aim
Determination of the Effect of Mango Leaf Extract on Metabolic Indices of Patients with Type 2 Diabetes including Fasting Blood Sugar, 2hpp, Lipid Profile, BMI

Design
This is a randomized Double-blinded clinical trial with two parallel groups in Phase 3. In this study 40 patients with type 2 diabetes referring to specialized clinic and Then, patients were randomly divided into two control and intervention groups.

Settings and conduct
This study will be carried out in the specialized clinic of Kerman University of Medical Sciences. In this study, patients were randomly divided into drug and placebo groups using randomization software. Patients and drug providers are not aware of the type of capsules they receive. At the beginning and at the end of the study, 10 ml of fasting venous blood was taken from all patients. Anthropometric characteristics data of patients will be recorded. At the beginning and end of the study, fasting glucose, 2hpp, fasting insulin, and lipid profiles will be determined.

Participants/Inclusion and exclusion criteria
Inclusion criteria: type 1 diabetes based on World Health Organization Guidelines from at least 6 months ago; taking oral hypoglycemic drugs; age 25-60 years old. Exclusion criteria: changes in blood glucose drugs from 2 months prior to study; insulin use; smoking; pregnancy; use of herbal medications; lactation; digestive and liver problems; hormonal problems such as thyroid dysfunction; heart problems; consumption drugs that interfere with blood sugar and lipid levels; such as non-steroidal anti-inflammatory drugs.

Intervention groups
Patients with age between 25 to 60 years old with type 2 diabetes receive 500 mg capsules containing mango leaf extract twice daily (before lunch and before dinner) for 45 days.

Main outcome variables
FBS; 2HPP; fasting insulin; lipid profiles; BMI

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180923041093N2**
Registration date: **2019-10-12, 1398/07/20**
Registration timing: **prospective**

Last update: **2019-10-12, 1398/07/20**
Update count: **0**

Registration date
2019-10-12, 1398/07/20

Registrant information

Name
Fatemeh sadat Hasheminasab

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 71 5333 8547

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-11-21, 1398/08/30

Expected recruitment end date
2020-01-20, 1398/10/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Effects of Mangifera indica extract supplement on metabolic status in type 2 diabetic patients

Public title
Effect of mango leaf on diabetes on lipid profiles

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Type 1 Diabetes According to the World Health Organization's online guide from 6 months ago Taking blood sugar lowering drugs

Exclusion criteria:
Changes in diabetes medications from 2 months before the study Insulin consumption Smoking Pregnancy Use of herbal medications Lactation Gastrointestinal and liver problems Hormonal problems such as thyroid dysfunction Cardiac problems Medications that interfere with blood sugar and lipid levels such as non-inflammatory drugs Steroid

Age
From **25 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
By random allocation software

Blinding (investigator's opinion)
Double blinded

Blinding description
Drug coding will be done by a third party and during the study, not everyone, including physicians, patients, and those responsible for drug delivery will be aware of the type of drug used and the placebo.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research ethic committee of Kerman University of Medical Sciences

Street address
Beginning of Ibn Sina Street, Beginning of Jihad Blvd., Somayeh Road (Tahmasebabad), Kerman

City
Kerman

Province
Kerman

Postal code
584-76175

Approval date
2019-04-21, 1398/02/01

Ethics committee reference number
IR.KMU.REC.1398.085

Health conditions studied

1

Description of health condition studied
Diabetes

ICD-10 code
E08

ICD-10 code description
Diabetes mellitus due to underlying condition

Primary outcomes

1

Description
Fasting blood sugar

Timepoint
Baseline and 45 days after the intervention

Method of measurement
Fasting serum Glucose concentration in mg/dl by kit

2

Description
2 hours post prandial

Timepoint
Baseline and 45 days after the intervention

Method of measurement
Fasting serum Glucose concentration in mg/dl by kit

3

Description
Fasting Insulin

Timepoint
Baseline and 45 days after the intervention

Method of measurement
Fasting serum Insulin concentration in µU/ml by kit

4

Description

Serum Teriglycerid

Timepoint

Baseline and 45 days after the intervention

Method of measurement

Fasting serum Teriglycerid concentration in mg/dl by kit

5

Description

Serum cholestrol

Timepoint

Baseline and 45 days after the intervention

Method of measurement

Fasting Serum cholestrol concentration in mg/dl by kit

6

Description

LDL Cholestrol

Timepoint

Baseline and 45 days after the intervention

Method of measurement

Fasting Serum HDL Cholestrol concentration in mg/dl, calculating by Friedewald formula

7

Description

HDL Cholestrol

Timepoint

Baseline and 45 days after the intervention

Method of measurement

Fasting Serum HDL Cholestrol concentration in mg/dl by kit

8

Description

Body mass index

Timepoint

Baseline and 45 days after the intervention

Method of measurement

Weight to square height ratio

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Mango leaf extract 500 mg, twice daily, for 45 days

Category

Treatment - Other

2

Description

Control group: Placebo 500 mg twice daily for 45 days

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Afzalipour Hospital

Full name of responsible person

Maryam Azimi

Street address

AfzaliPour Hospital, Adjacent to Bahonar University, AfzaliPour Landscape, Imam highway, Kerman

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Web page address

http://www.kmu.ac.ir/sitewizard/admin/wizard/Default.Aspx?PageId=3089

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Abbas Pardakhti

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kerman University of Medical Sciences

Proportion provided by this source

100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
Maryam Azimi

Position
Assistant professor

Latest degree
Ph.D.

Other areas of specialty/work
Traditional Medicine

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Full name of responsible person
Fatemeh Sadat Hasheminasab

Position
PhD student of Persian medicine

Latest degree
Medical doctor

Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document
After the completion of the study, the information on the main outcome will be shared.

When the data will become available and for how long
10 months after printing

To whom data/document is available
All researchers can take action.

Under which criteria data/document could be used
Data and results will be available to all researchers for research on diabetes.

From where data/document is obtainable
To email: hashemifa67@gmail.com

What processes are involved for a request to access data/document

The data will be provided to the applicant after a review and approval of the request within a month.

Comments