

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 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)

Phone

+98 71 5333 8547

Email address

hashemifa67@gmail.com

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 (Tahmasebad), 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 Triglycerid
Timepoint
Baseline and 45 days after the intervention
Method of measurement
Fasting serum Triglycerid 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
City
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Province
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7616913911
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Fax
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Email
dr.azimm@gmail.com
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
Street address
Kerman university of medical sciences, Haft-Bagh Highway
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Province
Kerman
Postal code
7616913555
Phone
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Fax
+98 34 3226 3857
Email
abpardakhty@kmu.ac.ir
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

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

Street address

Crossroad Amir kabir, jomhuri eslami Blvd

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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Latest degree

Ph.D.

Other areas of specialty/work

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Email**Person responsible for updating data****Contact****Name of organization / entity**

Kerman University of Medical Sciences

Full name of responsible person

Fatemeh Sadat Hasheminasab

Position

PhD student of Persian medicine

Latest degree

Medical doctor

Other areas of specialty/work

Traditional Medicine

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Faculty of Traditional Persian Medicine, Amir Kabir crossroad

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Email

hashemifa67@gmail.com

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