

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Sep 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**  
Kerman  
**Province**  
Kerman  
**Postal code**  
7616913911  
**Phone**  
+98 34 3132 8000  
**Fax**  
+98 34 1211 3426  
**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  
**City**  
Kerman  
**Province**  
Kerman  
**Postal code**  
7616913555  
**Phone**  
+98 34 3226 3855  
**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

**City**

Kerman

**Province**

Kerman

**Postal code**

7618843883

**Phone**

+98 34 3211 0860

**Email**

dr.azimm@gmail.com

**Person responsible for scientific 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

**City**

Kerman

**Province**

Kerman

**Postal code**

7618843883

**Phone**

+98 34 3211 0860

**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

**Street address**

Faculty of Traditional Persian Medicine, Amir Kabir crossroad

**City**

Kerman

**Province**

Kerman

**Postal code**

7618843883

**Phone**

+98 34 3211 0860

**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**