

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Effect of Morus Alba leaves's extract supplement on blood glucose, lipid profiles, HbA1c, insulin resistance ,inflammation factors and oxidative stress biomarkers in patients with type 2 diabetes

Protocol summary

Study aim

The aim of this study is to determine the effects of Mulberry alba leave extract on the metabolic profile, inflammatory factors, and biomarkers of oxidative stress and ALT and AST enzymes on patients with TDM2.

Design

A randomized, double-blind, controlled clinical trial on 60 patients. Computer-generated random numbers were utilized for random assignment.

Settings and conduct

60 eligible patients with type 2 diabetes and referred to outpatient Naghavi Clinic affiliated to Kashan University of Medical Sciences, Kashan, Iran will be selected in the study. Patients will be given 300 mg capsule of mulberry leaf extract twice a day (intervention group) or placebo (control group). Fasting blood samples will be taken from patients at the beginning of the study and 12 weeks after the intervention. Then, variables including fasting plasma glucose, serum insulin, HOMA-IR, lipid profile, QUICKI, CRP, NO, total antioxidant capacity, total plasma glutathione, MDA, hemoglobin A1C, and ALT and AST enzymes Will be measured.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with type 2 diabetes mellitus; aged 35-70 years. Exclusion criteria: Taking berry extract in the last three months; Changes in glucose-lowering drugs during the study; Taking anticoagulants; Pregnancy or lactation; Malignancies; Chronic liver disease.

Intervention groups

The intervention consists of taking mulberry extract supplement (300 mg) twice per a day during 12 weeks, which is prepared by the Pharmaceutical Company of Barij Essence in Kashan, Iran, previously confirmed by the Food and Drug Administration. The placebo capsules contains starch produced by the same company.

Main outcome variables

Fasting plasma glucose; serum insulin; HOMA-IR; lipid profile; QUICKI; CRP; NO; total antioxidant capacity; total plasma glutathione; MDA; hemoglobin A1C

General information

Reason for update

The updating process was done before publishing the paper to correct the registration information.

Acronym

IRCT registration information

IRCT registration number: **IRCT2016081312438N21**

Registration date: **2017-01-12, 1395/10/23**

Registration timing: **registered_while_recruiting**

Last update: **2022-04-29, 1401/02/09**

Update count: **2**

Registration date

2017-01-12, 1395/10/23

Registrant information

Name

Mohsen Taghizadeh

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Barij Research Center of Medicinal Herbs

Expected recruitment start date

2016-11-21, 1395/09/01

Expected recruitment end date

2017-01-22, 1395/11/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Morus Alba leaves's extract supplement on blood glucose, lipid profiles, HbA1c, insulin resistance ,inflammation factors and oxidative stress biomarkers in patients with type 2 diabetes

Public title

Effect of Morus Alba leaves's extract supplement on type 2 diabetes

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with type 2 diabetes mellitus Aged 35–70 years

Exclusion criteria:

Mulberry extract intake in the last three months
Changing in glucose-lowering medications Taking
anticoagulants during the study Pregnancy or lactating
Malignancies Chronic hepatic diseases

Age

From **35 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Computer-generated random numbers will be utilized for random assignment. Clinic-trained personnel will be performed all participant enrollment, random allocation and group assignment.

Blinding (investigator's opinion)

Double blinded

Blinding description

Randomization and allocation will be concealed from the researchers and participants until the final analyses are completed. Another person who is not involved in the trial and not aware of random sequences, will be assigned the participants to the numbered bottles of capsules.

Placebo

Used

Assignment

Parallel

Other design features

Randomized based on table of random numbers

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Kashan University of Medical Sciences

Street address

Kashan University Of Medical Sciences, Kashan

City

Kashan

Province

Isfahan

Postal code

8715973474

Approval date

2016-09-28, 1395/07/07

Ethics committee reference number

IR.KAUMS.REC.1395.57

Health conditions studied**1****Description of health condition studied**

Diabets type 2

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes**1****Description**

HOMA-IR

Timepoint

Before the beginning of the study and 12 weeks after

Method of measurement

Calculated with HOMA formula

Secondary outcomes**1****Description**

Fasting plasma glucose (FPG)

Timepoint

Before the beginning of the study and after 12 weeks.

Method of measurement

Enzymatic

2

Description

Insulin

Timepoint

Before the beginning of the study and after 12 weeks.

Method of measurement

ELISA

3

Description

QUICKI

Timepoint

Before the beginning of the study and after 12 weeks.

Method of measurement

Calculated with formula

4

Description

HbA1C

Timepoint

Before the beginning of the study and after 12 weeks.

Method of measurement

Immunofluorescence

5

Description

Triglycerides

Timepoint

Before the beginning of the study and after 12 weeks.

Method of measurement

Enzymatic

6

Description

Very low density lipoprotein (VLDL)-Cholesterol

Timepoint

Before the beginning of the study and after 12 weeks.

Method of measurement

Enzymatic

7

Description

Cholesterol

Timepoint

Before the beginning of the study and after 12 weeks.

Method of measurement

Enzymatic

8

Description

Low density lipoprotein (LDL)-Cholesterol

Timepoint

Before the beginning of the study and after 12 weeks.

Method of measurement

Enzymatic

9

Description

High density lipoprotein (HDL)-Cholesterol

Timepoint

Before the beginning of the study and after 12 weeks.

Method of measurement

Enzymatic

10

Description

Alanine transaminase (ALT)

Timepoint

Before the beginning of the study and after 12 weeks.

Method of measurement

Enzymatic

11

Description

Aspartate transaminase (AST)

Timepoint

Before the beginning of the study and after 12 weeks.

Method of measurement

Enzymatic

12

Description

C reactive protein (CRP)

Timepoint

Before the beginning of the study and after 12 weeks.

Method of measurement

ELISA

13

Description

Nitric oxide (NO)

Timepoint

Before the beginning of the study and after 12 weeks.

Method of measurement

Spectrophotometry

14

Description

Total antioxidant capacity (TAC)

Timepoint

Before the beginning of the study and after 12 weeks.

Method of measurement

Spectrophotometry

15

Description

Glutathione (GSH)

Timepoint

Before the beginning of the study and after 12 weeks.

Method of measurement

Spectrophotometry

16

Description

Malondialdehyde (MDA)

Timepoint

Before the beginning of the study and after 12 weeks.

Method of measurement

Spectrophotometry

Intervention groups

1

Description

Intervention group: 300 mg Morus Alba leaves's extract capsule, twice a day; 12 weeks; produced by Barij esans Co, Kashan, Iran.

Category

Treatment - Drugs

2

Description

Control group: Placebo capsule; twice a day; 12 weeks; produced by Barij esans Co, Kashan, Iran.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Outpatient Naghavi Clinic

Full name of responsible person

Zatollah Asemi

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Shahid Rajaee Avenue, Kashan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

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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

Kashan 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

Barij Research Center of Medicinal Herbs

Full name of responsible person

Dr.M. Taghizadeh

Position

PHD

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be 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

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

Clinical Study Report

Undecided - It is not yet known if there will be 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

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

Barij Research Center of Medicinal Herbs

Full name of responsible person

M.Mahlouji

Position

Clinical Reserch Expert

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address