Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 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 Mulbery 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
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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
Isfehan
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 lipoptotein (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 lipoptotein (LDL)-Cholesterol
Timepoint
Before the beginning of the study and after 12 weeks.
Method of measurement
Enzymatic

9

Description
High density lipoptotein (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
Street address
Shahid Rajaee Avenue, Kashan
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8715973474
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Email
asemi_r@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Dr Gholamali Hamidi
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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
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Nutrition
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Person responsible for updating data

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Ph.D.
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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