

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Effect of Trigonella foenum, Vaccinium arctostaphylos, Cichorium intybus, Matricaria chamomilla and Urtica dioica extract mixture on blood sugar control in type 2 diabetic patients.

Protocol summary

2019-04-28, 1398/02/08

Study aim

The determine of mixture of herbal extracts on blood sugar control in type 2 diabetic patients

Design

Two arm parallel group design of 100 patients, randomized trial with blinded outcome assessment in 2-3 clinical trial phase

Settings and conduct

Patients with type 2 diabetes who have include criteria and referred to a diabetes clinic affiliated to Mashhad University of Medical Sciences will randomly be included in the study and will be placed in two groups of drugs and placebo. The patients and researchers in this study were blinded in

Participants/Inclusion and exclusion criteria

Patients with type 2 diabetes who are being treated with dietary and medication

Intervention groups

To the intervention group, two 500 mg capsules of a mixture of herbal extracts are given daily and two 500 mg capsules of placebo are given daily to the control group.

Main outcome variables

FBS- Lipid profile- HbA1C- S GOT-SGPT- ALP- Creatinine

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170821035817N3**

Registration date: **2019-04-28, 1398/02/08**

Registration timing: **prospective**

Last update: **2019-04-28, 1398/02/08**

Update count: **0**

Registration date

Registrant information

Name

Maryam Yaghoubi

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-22, 1398/03/01

Expected recruitment end date

2020-05-21, 1399/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Trigonella foenum, Vaccinium arctostaphylos, Cichorium intybus, Matricaria chamomilla and Urtica dioica extract mixture on blood sugar control in type 2 diabetic patients.

Public title

Effect of Trigonella foenum, Vaccinium arctostaphylos, Cichorium intybus, Matricaria chamomilla and Urtica dioica extract mixture in treatment of diabetes.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diabetic patients treated with Dietary and hypoglycemic agents Blood HbA1c level 7.5-8.5 % Fasting blood glucose levels between 130 to 170 mg/dL Have diabetes for at least two years 40 to 60 years old

Exclusion criteria:

Patient with renal, hepatic and cardiac failure Patients with diabetic foot ulcer, gangrene, or any severe illness Painful diabetic neuropathy and depressed patients Smokers and alcoholic patients Patients who tend to change their exercise program or diet

Age

From **40 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Based on the include criteria and using the random sampling software, the subjects are divided into two groups of intervention and control. The drugs and placebo are placed in sealed envelopes.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participant-Clinical care- Researcher

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

No.18, Daneshgah St

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Mashhad

Province

Razavi Khorasan

Postal code

13944-91388

Approval date

2019-01-17, 1397/10/27

Ethics committee reference number

IR.MUMS.REC.1397.177

Health conditions studied

1

Description of health condition studied

Diabetes

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes

1

Description

Fasting blood glucose

Timepoint

Baseline and after 3 months at end of the study

Method of measurement

Blood Test

2

Description

HbA1C

Timepoint

Baseline and after 3 months at end of the study

Method of measurement

Blood Test

Secondary outcomes

1

Description

Cholesterol

Timepoint

Baseline and after 3 months at end of the study

Method of measurement

Blood Test

2

Description

Triglycerid

Timepoint

Baseline and after 3 months at end of the study

Method of measurement

Blood Test

3

Description

low-density lipoprotein

Timepoint

At starting of the study and after 3 months
Method of measurement
Blood low-density lipoprotein level will be determined in laboratory by commercially available

4

Description
High-density lipoprotein

Timepoint
At starting of the study and after 3 months

Method of measurement
Blood High-density lipoprotein level will be determined in laboratory by commercially available kit

5

Description
Aspartate aminotransferase

Timepoint
At starting of the study and after 3 months

Method of measurement
Blood aspartate aminotransferase level will be determined in laboratory by commercially available kit

6

Description
Alanine aminotransferase

Timepoint
At starting of the study and after 3 months

Method of measurement
Blood alanine aminotransferase level will be determined in laboratory by commercially available kit

7

Description
Blood urea nitrogen

Timepoint
At starting of the study and after 3 months

Method of measurement
Blood blood urea nitrogen level will be determined in laboratory by commercially available kit

8

Description
Creatinine

Timepoint
At starting of the study and after 3 months

Method of measurement
Blood creatinine level will be determined in laboratory by commercially available kit

9

Description
Alkaline phosphatase

Timepoint
At starting of the study and after 3 months

Method of measurement
Blood Alkaline phosphatase level will be determined in

laboratory by commercially available kit

Intervention groups

1

Description
Intervention group: Patients in this group receive a 500 mg capsule of herbal drug two times a day.

Category
Treatment - Drugs

2

Description
Control group: Patients in this group receive a 500 mg capsule of placebo two times a day.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabetes Clinic

Full name of responsible person

Zhila Taherzadeh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iranian academic center for education culture and research

Full name of responsible person

Reza Hajiaghazadeh

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Institute of Medicinal Plants, Kavosh Blvd., Supa Blvd., Poleh Kordan

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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
Iranian academic center for education culture and research
Proportion provided by this source
50
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

2

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
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Grant name
research/961490/1/3208
Grant code / Reference number
961490
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad University of Medical Sciences
Proportion provided by this source
50
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
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Zhila Taherzadeh
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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

There is no further information

When the data will become available and for how long

Not decided yet

To whom data/document is available

Not decided yet

Under which criteria data/document could be used

Not decided yet

From where data/document is obtainable

Not decided yet

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

Not decided yet

Comments