Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

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
2019-04-28, 1398/02/08

Registrant information
Name
Maryam Yaghoubi
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 51 3802 2077
Email address
yaghoubim6@mums.ac.ir

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 Scienses

Street address

No.18, Daneshgah St

City

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

Alkalin phosphatase

Timepoint

At starting of the study and after 3 months

Method of measurement

Blood Alkalin 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

Street address

No.18. Daneshgah ST.

City

Mashhad

Province

Razavi Khorasan

Postal code

13944-91388

Phone

+98 51 3841 2081

Fax

+98 51 3843 0249

Email

Taherzadehzh@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iranian academic center for education culture and research

Full name of responsible person

Reza Hajiaghaee

Street address

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

City

Karaj

Province

Alborz

Postal code

3365166571

Phone
+98 26 3476 4010

Fax
+98 26 3476 4021

Email
Huseini_fallah@yahoo.com

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
Zhila Taherzadeh

Street address
No.18, Dansshgah ST.

City
Mashhad

Province
Razavi Khorasan

Postal code
13944-91388

Phone
+98 51 3841 2081

Fax
+98 51 3843 0249

Email
Taherzadehzh@mums.ac.ir

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
Mashhad University of Medical Sciences

Full name of responsible person
Zhila Taherzadeh

Position
Associated Professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

Street address
No.18, Daneshgah ST.

City
Mashhad

Province
Razavi Khorasan

Postal code
9138813944

Phone
+98 51 3841 2081

Fax
+98 51 3843 0249

Email
TaherzadehZh@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Iranian academic center for education culture and research

Full name of responsible person
Hasan Fallah Huseini

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Pharmacy

Street address
Research Complex of Jahad Daneshgahi, Kavosh Boulevard, Supa Boulevard, 55th Kilometer of Tehran-Gazvin Freeway, Karaj, Iran.

City
Karaj

Province
Alborz

Postal code
31375-369

Phone
+98 26 3476 4018

Fax

+98 26 3871 3638

Email

huseini_fallah@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Iranian academic center for education culture and research

Full name of responsible person

Hasan FallahHuseini

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

Research Complex of Jahad Daneshgahi, Kavosh Boulevard, Supa Boulevard, 55th Kilometer of Tehran-Gazvin Freeway, Karaj, Iran.

City

Karaj

Province

Alborz

Postal code

3365166571

Phone

+98 26 3476 4018

Fax

+98 26 3476 4021

Email

huseini_fallah@yahoo.com

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