Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Investigating the Effects of a Herbal Mixture of tribulus terrestris, Silybum marianum ،Trigonella foenum-graecum and cinnamon zeylanicum on Blood Glucose in Type 2 Diabetes

Protocol summary

Study aim

Determine the effects of a herbal compound on the level of diabetes mellitus that can be used as a complementary therapy in diabetic patients.

Design

In this study, 60 males and females with type 2 diabetes who are eligible to enter the study are selected. Participants are randomly divided into two intervention and control groups and assigned a code to hide the intervention group of each participant.

Settings and conduct

This clinical trial will be carried out before and after 60 men and women with type 2 diabetes. At the beginning of the study, patients receive fasting blood samples and their total cholesterol, LDL, VLDL, HDL, triglyceride, fasting blood glucose, hemoglobin glycosylated, liver enzymes, BUN, creatinine are examined. Patients are asked to take a tablespoon of herbaceous saccharine for 2 months. Fasting venous blood samples are tested at the end of the first month. Blood parameters will be measured using common kits in the market and autoanalysers. Patients participating in the research will not pay for the cost of the herb, visits, and tests. The third party encodes as experts, patients and medications so that the participant will be assigned to the allocation of clinical and clinical care groups to the patient and blind drug compounds.

Participants/Inclusion and exclusion criteria

The participants are 60 males and females with type 2 diabetes. Patients who are at high risk for not controlling glucose with a fixed dose of drug are excluded from this study.

Intervention groups

Patients are asked to mix and take a tablespoon of herbal combination on a daily basis, twice before (before lunch and before dinner) with a glass of water and dough. A common diet for people with diabetes continues throughout the study. There is also a control group. In both groups, the usual hypoglycemic agents will continue throughout the study as in the previous procedure. Patients will be visited during the first week, and vital signs, glucose and possible side effects will be investigated. Fasting venous blood samples are tested at the end of the first month

Main outcome variables

TG, cholesterol, VLDL, HDL, LDL, fasting blood glucose, blood glucose two hours after food, glycosylated hemoglobin ALT, AST, blood creatinine, BUN.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090811002330N2**
Registration date: **2018-02-09, 1396/11/20**
Registration timing: **registered_while_recruiting**

Last update: **2018-02-09, 1396/11/20**
Update count: **0**

Registration date

2018-02-09, 1396/11/20

Registrant information

Name

Seyed Hadi Mousavi

Name of organization / entity

Mashahd University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 1800 2258

Email address

mousavih@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2016-12-01, 1395/09/11

Expected recruitment end date
2018-11-21, 1397/08/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the Effects of a Herbal Mixture of tribulus terrestris, Silybum marianum ،Trigonella foenum-graecum and cinnamon zeylanicum on Blood Glucose in Type 2 Diabetes

Public title
Study of the effects of plant composition on blood glucose in type 2 diabetic patients "

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Male and female type 2 diabetes

Exclusion criteria:
Patients who are at high risk for not controlling glucose with a fixed dose of drug are excluded from this study

Age
No age limit

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **60**
More than 1 sample in each individual
Number of samples in each individual: **1**
Three samples will be taken from each person. The first example at the beginning of the study. A second sample a week later and a third blood sample at the end of the first month.
Actual sample size reached: **180**
More than 1 sample in each individual
Actual sample size in each individual: **1**

Randomization (investigator's opinion)
Randomized

Randomization description
En Given that the herbal drug and the drug are placed in the same full capsule, it is natural that the patient and the assessing physician are not aware of the type of medication they receive. Randomization is done based on the round-robin software and each patient will be treated or controlled in the group

Blinding (investigator's opinion)
Double blinded

Blinding description
A third person encodes as experts, patients, and medications so that the participant remains blind to the allocation of clinical and clinical care groups to the patient and drug compounds

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Committee on Ethics in Biomedical Research of the University of Medical Sciencesپزشکی

Street address
Daneshgah Street- opposite Daneshgah 18- Quraishi Building

City
Mashhad

Province
Razavi Khorasan

Postal code
9138813944

Approval date
2017-10-14, 1396/07/22

Ethics committee reference number
IR.MUMS.REC.1396.230

Health conditions studied

1

Description of health condition studied
Type 2 diabetes

ICD-10 code
E10-E14

ICD-10 code description
Endocrine, nutritional and metabolic diseases

Primary outcomes

1

Description
TG

Timepoint
Beginning of study. A week after taking the medication. End of the first month of experiment

Method of measurement
Measurement of blood parameters using common kits in the market and Autoanalyser

2

Description
cholesterol
Timepoint
Beginning of study. A week after taking the medication. End of the first
Method of measurement
Measurement of blood parameters using common kits in the market and Autoanalyser

3

Description
LDL
Timepoint
Beginning of study. A week after taking the medication. End of the first
Method of measurement
Measurement of blood parameters using common kits in the market and Autoanalyser

4

Description
HDL
Timepoint
Beginning of study. A week after taking the medication. End of the first
Method of measurement
Measurement of blood parameters using common kits in the market and Autoanalyser

5

Description
VLDL
Timepoint
Beginning of study. A week after taking the medication. End of the first
Method of measurement
Measurement of blood parameters using common kits in the market and Autoanalyser

6

Description
fasting blood glucose
Timepoint
Beginning of study. A week after taking the medication. End of the first
Method of measurement
Measurement of blood parameters using common kits in the market and Autoanalyser

7

Description
blood glucose two hours after food
Timepoint
Beginning of study. A week after taking the medication. End of the first
Method of measurement
Measurement of blood parameters using common kits in the market and Autoanalyser

8

Description
glycosylated hemoglobin
Timepoint
Beginning of study. A week after taking the medication. End of the first
Method of measurement
Measurement of blood parameters using common kits in the market and Autoanalyser

9

Description
ALT
Timepoint
Beginning of study. A week after taking the medication. End of the first
Method of measurement
Measurement of blood parameters using common kits in the market and Autoanalyser

10

Description
AST
Timepoint
Beginning of study. A week after taking the medication. End of the first
Method of measurement
Measurement of blood parameters using common kits in the market and Autoanalyser

11

Description
blood creatinine
Timepoint
Beginning of study. A week after taking the medication. End of the first
Method of measurement
Measurement of blood parameters using common kits in the market and Autoanalyser

12

Description
BUN
Timepoint
Beginning of study. A week after taking the medication. End of the first
Method of measurement
Measurement of blood parameters using common kits in the market and Autoanalyser

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients are asked to mix and take a tablespoon of herbal combination on a daily basis, twice before (before lunch and before dinner) with a glass of water and dough. During the study, patients are asked to continue to have a regular diet for diabetics.
Category
Treatment - Drugs

2

Description
Control group: Control group do not receive herbal medicine
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
School of Medicine of Mashhad
Full name of responsible person
Dr. Seyed Hadi Mousavi
Street address
Vakil Abad Ave. School of Medicine
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948564
Phone
+98 51 3882 9267
Fax
+98 51 3800 2467
Email
MousaviH@mums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr. Mohsen Tafaghodi
Street address
University Street. Opposite University 18
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Phone
+98 51 3882 9267
Fax
+98 51 3800 2467
Email
tafaghodim@mums.ac.ir
Grant name
Grant code / Reference number
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
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
Mashhad University of Medical Sciences
Full name of responsible person
Dr.Seyed Hadi Mousavi
Position
Assistant Professor of Mashhad Medical School
Latest degree
Ph.D.
Other areas of specialty/work
Others
Street address
Vakil Abad Street
City
Mashhad
Province
Razavi Khorasan
Postal code
9177948564
Phone
+98 51 3882 9267
Fax
+98 51 3800 2467
Email
MousaviH@mums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr.Seyed Hadi Mousavi
Position

Assistant Professor . Head of the Toxicology Research Center

Latest degree
Ph.D.

Other areas of specialty/work
Others

Street address
Vakil Abad

City
Mashhad

Province
Razavi Khorasan

Postal code
9177948564

Phone
+98 51 3882 9267

Fax
+98 51 3800 2467

Email
MousaviH@MUMS.AC.IR

Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Fatemeh Ariakia

Position
MA

Latest degree
Master

Other areas of specialty/work
Biochemistry

Street address
Vakil Abad

City
Mashhad

Province
Razavi Khorasan

Postal code
9177948564

Phone
+98 51 3882 9267

Fax
+98 51 3800 2467

Email
MousaviH@mums.ac.ir

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
Yes - There is 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
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Data and results will be published in the form of a paper after identification of the participants in the trial

When the data will become available and for how long
After completing the sampling and analysis of the data and six months after the publication of the article

To whom data/document is available
After the publication of this article, access to data is open to students and researchers

Under which criteria data/document could be used
In order to produce a cheap and effective drug that can reduce the side effects of treatment in addition to improving blood glucose control by chemical agents. Data will be available if the mixture causes a decrease in blood glucose levels in diabetic patients.

From where data/document is obtainable
Dr. Seyed Hadi Mousavi.Vakilabad Street. Mashhad Medical School. The first floor of the Pharmacology Department

What processes are involved for a request to access data/document
Request is sent by e-mail. Or receive a data file by visiting Mashhad Medical School and during the administrative process of the Mashhad Medical Sciences Faculty

Comments