Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the rhubarb plant extract compared to placebo on oxidative stress, fasting blood glucose, apolipoprotein B, apolipoprotein A1 and insulin levels in patients with type 2 diabetes

Protocol summary

Summary

A double-blind study in which the patients and the researchers are not informed of the types of intervention or of the grouping of the patients will be conducted at the Endocrine and Metabolism Research Center and the Diabetes Unit of Shariati Hospital. Only 30-60- year old patients having type 2 diabetes with fasting blood glucose of greater than 126 mg/dl enter the project, and people suffering from hyperglycemia caused by diseases other than diabetes and patients treated with insulin are excluded from it. Sixty patients with type 2 diabetes will be divided randomly(by block randomization) into three 20-member groups receiving aqueous extract of rhubarb, alcoholic extract of rhubarb, or placebo, for 6 weeks. Similar appearance containers each containing 135 drug or placebo capsules with a special code will be delivered to the patients by the therapist of the project and the special code on each container will be recorded in the file of the related patient. Each member of the three groups will receive a container with 135 capsules, with every capsule containing 450 mg of the aqueous extract, of the alcoholic extract, or of the placebo. Each patient will take three capsules every day. The patients in all three groups are tested for the concentrations of malondialdehyde, high sensitivity C-reactive protein, fasting blood glucose, apolipoprotein B, apolipoprotein A-1, and fasting insulin at beginning and at end of the 6th week of study

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201410142709N31**
Registration date: **2014-12-11, 1393/09/20**
Registration timing: **prospective**
Last update:
Update count: **0**

Registration date

2014-12-11, 1393/09/20

Registrant information

Name

Farzad Shidfar

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Iran University of Medical Sciences-Shahid Hemmat Expressway,Central building of Iran University of Medical Sciences

Expected recruitment start date

2015-04-04, 1394/01/15

Expected recruitment end date

2015-09-06, 1394/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the rhubarb plant extract compared to placebo on oxidative stress, fasting blood glucose, apolipoprotein B, apolipoprotein A1 and insulin levels in patients with type 2 diabetes

Public title
Effect of rhubarb in diabetes type 2
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: 30-60-year old patients with fasting blood glucose of greater than 126 mg/dl are included in the project. Exclusion criteria: Patients with hyperglycemia caused by diseases other than diabetes, patients suffering from liver, thyroid and kidney diseases, patients being treated with insulin, taking β-blockers and lipid-lowering drugs, consuming alcoholic drinks, having severe, acute, active infectious diseases when blood samples are taken, and patients who are hospitalized during the study are excluded from the study
Age
From **30 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
Three types of capsules are used in this study: (1) aqueous extract of rhubarb, (2) alcoholic extract of rhubarb, and (3) placebo.The aqueous extract of rhubarb, alcoholic extract of rhubarb, and placebo are as similar capsules with same color and appearance and packaged in similar containers and therefore the patients are not aware of the type of capsules which they take .Also, the researchers are not aware of type of capsules and name of groups. Therefore, this will be a double-blind study.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Iran University of Medical Sciences
Street address
The Central Office, Iran University of Medical sciences, Shahid Hemmat Expressway, between Chamran and Sheikh Fazlollah Expressway
City
Tehran
Postal code
Approval date
2014-10-12, 1393/07/20
Ethics committee reference number
24367

Health conditions studied

1

Description of health condition studied
Diabetes type 2
ICD-10 code
E10, E11,
ICD-10 code description
Insulin-dependent diabetes mellitus, Non-insulin-dependent diabetes mellitus, Malnutrition-related diabetes mellitus, Other specified diabetes mellitus, Unspecified diabetes mellitus

Primary outcomes

1

Description
Body Mass Index
Timepoint
Before and 6 weeks after intervention
Method of measurement
SECA,Kilogram per meter Square

2

Description
malondialdehyde
Timepoint
Before intervention and 6 weeks after intervention
Method of measurement
Spectrophotometry, mmol/L

3

Description
High sensitivity c-reactive protein
Timepoint
Before and 6 weeks after intervention
Method of measurement
immunoturbidimetry, mg/dl

4

Description
Fasting Blood Sugar
Timepoint
Before and 6 weeks after intervention
Method of measurement
glucose oxsidase , mg/dl

5

Description
Apolipoprotein B
Timepoint
Before and 6 weeks after intervention
Method of measurement
immunoturbidimetry, mg/dl

6

Description
Apolipoprotein A1
Timepoint
Before and 6 weeks after intervention
Method of measurement
immunoturbidimetry, mg/dl

7

Description
Insulin level
Timepoint
Before and 6 weeks after intervention
Method of measurement
enzymatic, mg/dl

Secondary outcomes

1

Description
Blood Pressure
Timepoint
Before and 6 weeks after intervention
Method of measurement
Mercury Sphygmomanometer, mmHg

Intervention groups

1

Description
Intervention group 1: Every day, members of the intervention group 1 receive three 450 mg oral capsules of the aqueous extract of rhubarb for six weeks which is made at School of Pharmacy, Shahid Beheshti University of Medical Sciences.
Category
Treatment - Drugs

2

Description
control group: Every day, members of the control group receive three 450 mg oral capsules of the placebo for six weeks which is made at School of Pharmacy, Shahid Beheshti University of Medical Sciences.
Category
Placebo

3

Description
Intervention group 2: Every day, members of the intervention group 1 receive three 450 mg oral capsules of the alcoholic extract of rhubarb for six weeks which is made at School of Pharmacy, Shahid Beheshti University of Medical Sciences.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shariati Hospital, Tehran
Full name of responsible person
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research, Iran University of Medical Sciences,
Full name of responsible person
Dr. Seyed Ali Javad Mousavii- Vice Chancellor for research, Iran University of Medical Sciences
Street address
5th floor, the Office of the Vice Chancellor for research, the Central Office, Iran University of Medical Sciences, Shahid Hemmat Expressway, between Chamran and Sheikh Fazlollah Expressway
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for research, Iran University of Medical Sciences,
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Farzad Shidfar

Position
Ph.D- Faculty member of Iran University of Medical Sciences

Other areas of specialty/work

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School of Health, Iran University of Medical Sciences,Shahid Hemmat Expressway, between Chamran and Sheikh Fazlollah Expressway.

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Web page address

Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty