Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effects of Berberis Integrima on blood biochemical factors in patients with type 2 dibetes

Protocol summary

Summary

After approval, permission from the university ethic committee and the preparation of capsules containing extracts of medicinal plants in question, we referred to specialized clinics of Prophet Muhammad and Imam Ali of University of Medical Sciences, 80 type 2 diabetic patients after the detection, diagnoses and getting the consent were randomly assigned to 2 groups . In the both groups, patients will receive the routine medication needed to control their diabetes . In addition to these drugs, patients in the first group (control group), placebo, the second group received 3 capsules weighting 400 mg of the fruit of Berberis vulgaris extract daily and orally for 2 months in 3 meals. At baseline, one month after the start of the project and at the end of the study some blood biochemical tests and urine analysis will be done for all patients with.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016041727438N1**
Registration date: **2016-05-20, 1395/02/31**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2016-05-20, 1395/02/31

Registrant information

Name

Mohammad Rahimi Madiseh

Name of organization / entity

Shahrekord Medical University of Sciences

Country

Iran (Islamic Republic of)

Phone

+98 38 3333 5648

Email address

m_rahimi7@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahrekord University Of Medical Sciences

Expected recruitment start date

2016-05-21, 1395/03/01

Expected recruitment end date

2016-07-20, 1395/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Berberis Integrima on blood biochemical factors in patients with type 2 dibetes

Public title

Effects of Berberis Integrima on type 2 dibetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: diagnosis of type 2 diabetes patients; age between 30 to 60 years; fasting blood sugar ≥126mg / dl; venous plasma glucose 2 hours after ingestion of 75 g glucose ≥200mg / dl; not receiving insulin; HBA1C from 7 to 8.5 percent; duration of diabetes diagnosis be less than 10 years; only using the blood glucose lowering drugs. Exclusion criteria: age less than 30 and more than 60 years; insulin taking; smoking; chronic cardiovascular disease; chronic renal disease; triglycerides more than 500 mg / d; pregnancy; use of anticoagulant drugs (except aspirin); chronic liver disease other than fatty liver; advanced diabetic

retinopathy; kidney failure; heart failure; hemorrhagic stroke; high and low work hypothyroidism.

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: **80**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shahrekord University Of Medical Sciences

Street address
Shahrekord University Of Medical Sciences, Kashani street, Shahrekord

City
Shahrekord

Postal code
8813833435

Approval date
2016-03-08, 1394/12/18

Ethics committee reference number
IR.SKUMS.REC.1394.304

Health conditions studied

1

Description of health condition studied
Type 2 diabetes

ICD-10 code
E11

ICD-10 code description
Type 2 diabetes mellitus

Primary outcomes

1

Description
Fast blood suger

Timepoint
Baseline and after 2 months (end of the study)

Method of measurement
Blood sampling and blood glucose measurement

2

Description
HbA1C

Timepoint
Baseline and after 2 months (end of the study)

Method of measurement
Blood sampling and measurement of blood

3

Description
HDL-C

Timepoint
Baseline and after 2 months (end of the study)

Method of measurement
Blood sampling and measurement of blood

4

Description
LDL-C

Timepoint
Baseline and after 2 months (end of the study)

Method of measurement
Blood sampling and measurement of blood

5

Description
TG

Timepoint
Baseline and after 2 months (end of the study)

Method of measurement
Blood sampling and measurement of blood

6

Description
Total Chol

Timepoint
Baseline and after 2 months (end of the study)

Method of measurement
Blood sampling and measurement of blood

7

Description
VLDL

Timepoint
Baseline and after 2 months (end of the study)

Method of measurement
Calculation

8

Description
BUN
Timepoint
Baseline and after 2 months (end of the study)
Method of measurement
Blood sampling and measurement of blood

9

Description
cratinine
Timepoint
Baseline and after 2 months (end of the study)
Method of measurement
Blood sampling and measurement of blood

10

Description
AST
Timepoint
Baseline and after 2 months (end of the study)
Method of measurement
Blood sampling and measurement of blood

11

Description
ALT
Timepoint
Baseline and after 2 months (end of the study)
Method of measurement
Blood sampling and measurement of blood

12

Description
Patient weight
Timepoint
Baseline and after 2 months (end of the study)
Method of measurement
Using the scale

13

Description
length of patient
Timepoint
Baseline and after 2 months (end of the study)
Method of measurement
Using a tape measure fixed on the wall (on the scale)

14

Description
BMI
Timepoint
Baseline and after 2 months (end of the study)
Method of measurement
Calculation

Secondary outcomes

1

Description
HDL-C
Timepoint
Baseline and end of the study
Method of measurement
Blood and serum isolated from blood

2

Description
LDL-C
Timepoint
Baseline and end of the study
Method of measurement
Blood and serum isolated from blood

3

Description
Triglycerides
Timepoint
Baseline and end of the study
Method of measurement
Blood and serum isolated from blood

4

Description
Total cholesterol
Timepoint
Baseline and end of the study
Method of measurement
Blood and serum isolated from blood

5

Description
VLDL
Timepoint
Baseline and end of the study
Method of measurement
Computing

6

Description
BUN
Timepoint
Baseline and end of the study
Method of measurement
Blood and serum isolated from blood

7

Description
Cratinine
Timepoint
Baseline and end of the study
Method of measurement

Blood and serum isolated from blood

8

Description
AST
Timepoint
Baseline and end of study
Method of measurement
Blood and serum isolated from blood

9

Description
ALT
Timepoint
Baseline and end of the study
Method of measurement
Blood and serum isolated from blood

10

Description
Weight
Timepoint
Baseline and end of the study
Method of measurement
Using the same and standardized scale

11

Description
BMI
Timepoint
Baseline and end of the study
Method of measurement
Computing

Intervention groups

1

Description
Each diabetic patients in the control group, in addition to routine type 2 diabetic patients drugs, will receive daily 3 placebo capsules at 3 in the morning, noon and night .
Category
Placebo

2

Description
Each diabetes patient in the intervention group, in addition to routines medication of type 2 diabetic, will receive the daily 3 capsules of 400 mg, containing the extract of the fruit of Berberis vulgaris 3 times in the morning, noon and night for two months .
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Clinic of Imam Ali (AS)
Full name of responsible person
Mohammad Rahimi Madiseh
Street address
Shariati Street, Basij Square
City
Shahrekord

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahrekord University Of Medical Sciences
Full name of responsible person
Doctor Kamal Solati
Street address
Vice Chancellor for Research and Technology, Shahrekord University of Medical Sciences, Kashani street
City
Shahrekord
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahrekord 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
Shahrekord University Of Medical Sciences
Full name of responsible person
Mohammad Rahimi Madiseh
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PhD student
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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