

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effects of Berberis Integrina on blood biochemical factors in patients with type 2 diabetes

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 Integrina on blood biochemical factors in patients with type 2 diabetes

Public title

Effects of Berberis Integrina on type 2 diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: diagnosis of type 2 diabetes patients; age between 30 to 60 years; fasting blood sugar ≥ 126 mg / dl; venous plasma glucose 2 hours after ingestion of 75 g glucose ≥ 200 mg / 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

Position

PhD student

Other areas of specialty/work

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Medical Plants Research Center, University of Medical Sciences, Rahmatiyeh

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Person responsible for scientific inquiries

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Full name of responsible person
Mahmoud Rafeian-Kopaei

Position
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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