

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Sep 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  $\geq 126$ mg / dl; venous plasma glucose 2 hours after ingestion of 75 g glucose  $\geq 200$ 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

#### Street address

Medical Plants Research Center, University of Medical  
Sciences, Rahmatiyeh

#### City

Shahrekord

#### Postal code

**Phone**  
+98 38 3334 6722  
**Fax**  
**Email**  
m\_rahimi7@yahoo.com  
**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Medical Plants Research center, Shahrekord  
University of Medical Sciences

**Full name of responsible person**  
Mahmoud Rafeian-Kopaei

**Position**  
professor

**Other areas of specialty/work**

**Street address**  
Medical Plants Research center, Shahrekord  
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## Person responsible for updating data

### Contact

**Name of organization / entity**

Shahrekord University Of Medical Sciences

**Full name of responsible person**

Mohammad Rahimi Madiseh

**Position**

ph.D student

**Other areas of specialty/work**

**Street address**

Medical Plants Research Center, University of Medical  
Sciences, Rahmatiyeh

**City**

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8813833435

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**Fax**

**Email**

m\_rahimi7@yahoo.com

**Web page address**

## 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*