

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Investigation of the safety profile , metabolic and pharmacodynamic effect of extract of Berberis aristata versus metformin tablet on blood glucose in patients with type 2 diabetic mellitus.

#### Protocol summary

##### Summary

Aim: Reviewing the safety rate and metabolic effects of administration of methanolic extract of Berberis aristata root (Local Barberry) in comparison with metformin tablets in type 2 diabetic patients Design: Randomized clinical trial, double blinded, control by placebo, single center Implementation method: Sixty diabetic clinic outpatients with Balance blocked Randomization are divided to two groups of 30 in each (with loss retention) that in the first group (Group A) patients take Berberis aristata root methanolic extract wick is made in capsule form and placebo of metformin tablet orally and they are controlled by diet and exercise. The second group (Group B), which is the control group, takes two 500-mg Metformin tablets twice in a day plus placebo of berberis aristata capsules and they are controlled by diet and exercise. Blood and urine samples, clinical examination and questionnaire in two studied groups are reviewed in time periods of 0, 15, 45 and 90 days of treatment. Participants: diabetic clinic outpatients (Inclusion criteria: type 2 diabetics, age of 18-75 years, Exclusion criteria: patients with other chronic diseases, treatment by insulin) Interventions: Administration of methanolic extract of Berberis aristata root and Metformin Main outcome: Fasting blood sugar, 2-hours post breakfast blood sugar, Glycated hemoglobin Other variables from complications viewpoint: Creatinine, Triglyceride, Cholesterol, High Density Lipoprotein, alanine aminotransferase, aspartate aminotransferase, alkaline phosphatase Bilirubin, Thromboplastin Time, Prothrombin Time, complete blood cell Count

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201207191774N5**

Registration date: **2014-08-15, 1393/05/24**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2014-08-15, 1393/05/24

##### Registrant information

###### Name

Mojgan Sanjari

###### Name of organization / entity

Kerman University of Medical Science

###### Country

Iran (Islamic Republic of)

###### Phone

+98 34 1322 2506

###### Email address

msanjari@kmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Metformin and placebo are prepared by EXIR company and physiology investigation center has assumed the responsibility of the other expenses .

##### Expected recruitment start date

2013-12-22, 1392/10/01

##### Expected recruitment end date

2014-12-22, 1393/10/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Investigation of the safety profile , metabolic and pharmacodynamic effect of extract of Berberis aristata versus metformin tablet on blood glucose in patients with type 2 diabetic mellitus.

**Public title**

Investigation of Berberis aristata root effect versus metformin tablet on blood sugar in diabetic patients .

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: Newly diagnosed type 2 diabetes based on ADA 2011 [14], 18-75 years old, Both sexes, Capable to swallow, No other tablet except metformine, No insulin therapy, No chronic inflammatory disease [17]  
Exclusion criteria: Fasting blood sugar more than 250 mg/dl, HbA1C more than 10%, Patients with chronic complications of diabetes, Pregnancy, Lactation, Known liver, renal or neurologic diseases (based on clinical examination, interview with patient or previously endorsed documents with the patients).

**Age**

From **18 years** old to **75 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Not 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**

Ethics Committee Vice chancellor for Research and Technology of kerman university of medical science

**Street address**

In front of Besat clinic, the beginning of Ebn-e-Sina street, the beginning of Jahad Boulevard, Tahmasb Abad crossroads, Physiology research center, Vice chancellor for Research and Technology of University of Medical Sciences, kerman

**City**

kerman

**Postal code****Approval date**

2012-07-15, 1391/04/25

**Ethics committee reference number**

10.61.806

**Health conditions studied****1****Description of health condition studied**

Diabet mellitus

**ICD-10 code**

E11

**ICD-10 code description**

non insulin dependent diabetes mellitus

**Primary outcomes****1****Description**

plasma glucose

**Timepoint**

during of study

**Method of measurement**

blood sample

**2****Description**

hba1c

**Timepoint**

after 3 month

**Method of measurement**

blood sample

**3****Description**

fructose amin

**Timepoint**

after 2 weeks

**Method of measurement**

blood sample

**Secondary outcomes****1****Description**

Laboratory Tests

**Timepoint**

after 0-15-45-90 days

**Method of measurement**

blood and urine sample

**2****Description**

weight and blood prussre and others

## Timepoint

after 0-15-45-90 days

## Method of measurement

Barometer system and standard weight

## Intervention groups

### 1

#### Description

first group:intervention group( Berberis aristata capsule and metformin placebo tablet) use Berberis aristata capsule (methanol extract of Berberis aristata root ) as 500mg daily for three months and are in control of exercise and diet .

#### Category

Treatment - Drugs

### 2

#### Description

second group:control group (metformin tablet and Berberis aristata placebo capsule) use metformin tablet as 500mg two times a day after breakfast and dinner for three month and are in control of exercise and diet.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Kerman Afzalipour Hospital

##### Full name of responsible person

Dr. Behrang Shamsinezhad Babaki

##### Street address

AfzaliPour Hospital, Adjacent to Bahonar University, AfzaliPour Landscape, Imam highway, Kerman

##### City

Kerman

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Physiology research center, Vice chancellor for Research and Technology of kerman medical University

##### Full name of responsible person

Dr.Hamid Najafi pour

##### Street address

Physiology research center, Vice chancellor for Research and Technology of University of Medical Sciences, In front of Besat clinic, the begining of Ebn-e-Sina street, the begining of Jahad Boulevard, Tahmasb Abad crossroads, Kerman

##### City

Kerman

## Grant name

## Grant code / Reference number

## Is the source of funding the same sponsor organization/entity?

Yes

## Title of funding source

Physiology research center, Vice chancellor for Research and Technology of kerman medical University

## 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

Kerman Afzalipour Hospital

#### Full name of responsible person

Dr. Mojgan Sanjari

#### Position

Associated professor

#### Other areas of specialty/work

#### Street address

AfzaliPour Hospital, Adjacent to Bahonar University, AfzaliPour Landscape, Imam highway, Kerman

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#### Postal code

7616913911

#### Phone

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#### Fax

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#### Email

msanjari@kmu.ac.ir

#### Web page address

<http://www.kmu.ac.ir/sitewizard/admin/wizard/Default.aspx?Pageld=3089>

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Kerman Afzalipour Hospital

#### Full name of responsible person

Dr. Mojgan Sanjari

#### Position

Associated professor

#### Other areas of specialty/work

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<http://www.kmu.ac.ir/sitewizard/admin/wizard/Default.aspx?Pageld=3089>

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Kerman Afzalipour Hospital  
**Full name of responsible person**  
Dr. Mojgan Sanjari  
**Position**  
Associated Professor  
**Other areas of specialty/work**  
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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*