

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

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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

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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

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Person responsible for scientific inquiries

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Person responsible for updating data

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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