Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 artistata 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 artistata root methanolic extract wich 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 artistata 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 begining of Ebn-e-Sina street, the begining 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
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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 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