

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of Berberis root active component (Berberine) on blood sugar control in patients with Type2 Diabetes.

Protocol summary

Summary

Target study: Hypoglycemic effect of Berberis Root active component (Berberine) in patients with Type2 Diabetes. our study Will be double-blind, Randomized and controlled -placebo. Inclusion criteria: Age 30-65 years; HbA1C 7-8.5; Fasting Blood Sugar 126 -200; diagnosis of Diabetes less than 10 years; Only use oral blood glucose lowering drugs. Exclusion criteria: triglyceride More Than 500 ;pregnancy ; Consumers of anticoagulants drugs (except Aspirin); chronic liver disease except fatty liver disease; proliferative Diabetic retinopathy; Renal Failure; Heart failure; Hemorrhagic strokes; hypothyroidism and hyperthyroidism; treatment with Insulin. in this study 84 patients divided into Block - random quaternary Two groups (forty-two patients in addition to Previous drugs and new life style, Herbal Berberine capsules 500 mg twice per day every twelve hours and forty-two other patients in addition to previous drugs and new life, style placebo capsules 500 mg twice per day every twelve hours for four weeks is given). at baseline of study Blood pressure, height and Body mass index calculated and 2hour post prandial, fasting Blood Sugar, fructosamine, lipid profile, fasting blood insulin, Blood Urea Nitrogen, Creatinine, and liver enzymes take sampling, then the indexes HOMA-IR, HOMA-β% will calculated. And after fourth week All tests were performed again, and Hypoglycemic effect of Berberine Will be discussed .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013040712933N1**
Registration date: **2013-06-12, 1392/03/22**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-06-12, 1392/03/22

Registrant information

Name

Zahra Mehraban

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 1320 9667

Email address

mehraban.z@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Ahvaz Jundishapur University of Medical Sciences.

Expected recruitment start date

2013-05-07, 1392/02/17

Expected recruitment end date

2013-06-07, 1392/03/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Berberis root active component (Berberine) on blood sugar control in patients with Type2 Diabetes.

Public title

Effect of Berberis root active component (Berberine) in patients with Type2 Diabetes.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age 30-65 years; HbA1C 7-8.5; Fasting Blood Sugar 126 -200; diagnosis of Diabetes less than 10 years; Only use oral blood glucose lowering drugs .
Exclusion criteria: Fasting Blood Sugar More Than 200; HbA1C More Than 8.5 ;triglyceride More Than 500; pregnancy; Consumers of anticoagulants drugs (except Aspirin); chronic liver disease except fatty liver disease; proliferative Diabetic retinopathy; Renal Failure; Heart failure; Hemorrhagic strokes; hypothyroidism and hyperthyroidism; treatment with Insulin.

Age

From **30 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **84**

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**

Ethics Committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Esfand St, Golestan Blvd .

City

Ahvaz

Postal code

6136845348

Approval date

2013-03-09, 1391/12/19

Ethics committee reference number

ETH-705

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

Type 2 Diabet

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

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

Fasting Blood Sugar

Timepoint

baseline , after four weeks.

Method of measurement

Blood samples from patients, mg/dl

2**Description**

2hpp(2 hour post prandial)

Timepoint

baseline , after four weeks.

Method of measurement

Blood samples from patients, mg/dl

3**Description**

Fructosamine

Timepoint

baseline , after four weeks.

Method of measurement

Blood samples from patients ,umol

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

Lipid profile

Timepoint

baseline , after four weeks.

Method of measurement

Blood samples from patients,Mg per deciliter

2**Description**

Blood pressure

Timepoint

baseline , after four weeks.

Method of measurement

Manometer, mmHg

3**Description**

Body Mass Index

Timepoint

baseline , after four weeks.

Method of measurement

Scale,Meter,Kg/m2

Intervention groups

1

Description

Intervention group: Forty-two Patients in addition to previous medications, a new lifestyle, Herbal Capsule Berberine 500 mg twice per day, every twelve hours for four weeks.

Category

Placebo

2

Description

Control group: Forty-two Patients in addition to previous medications, a new lifestyle, placebo Capsule 500 mg twice per day, every twelve hours for four weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabetes Clinic Department , Golestan Hospital

Full name of responsible person

Zahra Mehraban,MD

Street address

Farvardin St,Golestan Blvd, Golestan Hospital

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research Ahvaz University of Medical Sciences

Full name of responsible person

Mostafa Fegghi, MD

Street address

Esfand St, Golestan Blvd.

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Grant name

-

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research Ahvaz 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

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Zahra Mehraban, MD

Position

Resident of Internal Medicine

Other areas of specialty/work

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

Mrs Homeyra Rashidi , MD

Position

Associated Professor

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Position

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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