Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 critria: 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 Bady 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
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Iran (Islamic Republic of)
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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 critria: 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
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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 Feghhi, MD
Street address
Esfand St, Golestan Blvd.
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Ahvaz
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
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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