Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

The randomized.placebo controlled clinical trial of Berberis vulgaris hydroalcoholic root extract capsules on glycaemic and lipid parameters in type 2 diabetes mellitus patients

Protocol summary

Summary

Target study: Hypoglycemic and hypolipidemic effect of Berberis vulgaris hydroalcoholic Root extract in patients with Type2 Diabetes. Our study was double-blind, Randomized and placebo controlled. Inclusion criteria: Age 20-65 years; HbA1C <8.5%; Fasting Blood Sugar <200; diagnosis of Diabetes less than 1 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; Renal Failure; Heart failure; Hemorrhagic strokes; hypothyroidism and hyperthyroidism. In this study 84 patients divided into Block - random quaternary two groups (in forty-two patients in addition to their prescibed drugs treated with Berberis vulgaris capsules 500 mg twice per day every twelve hours and in forty-two other patients in addition to their prescibed drugs received placebo capsules 500 mg twice per day every twelve hours for six weeks). at baseline of study Blood pressure, Body mass index, waist-to-hip ratio was measured and blood samples for laboratory tests include: fasting Blood Sugar,2hour post prandial, fructosamine, lipid profile, fasting blood insulin, Blood Urea Nitrogen, Creatinine, and liver enzymes tests were taken, then the indexes HOMA-IR and HOMA-β% was calculated. After sixth week all tests were performed again, and Hypoglycemic and hypolipidemic effect of Berberis vulgaris hydroalcoholic Root extract discussed

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201504264610N3**
Registration date: **2015-05-03, 1394/02/13**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2015-05-03, 1394/02/13

Registrant information

Name
Foroogh Namjoyan
Name of organization / entity
School of pharmacy
Country
Iran (Islamic Republic of)
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Email address
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Recruitment status

Recruitment complete

Funding source

Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2014-03-06, 1392/12/15

Expected recruitment end date

2014-08-11, 1393/05/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The randomized.placebo controlled clinical trial of Berberis vulgaris hydroalcoholic root extract capsules on glycaemic and lipid parameters in type 2 diabetes mellitus patients

Public title

Effect of hydroalcoholic root extract of berberis vulgaris in patients with Type2 Diabetes.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age 20-65 years; HbA1C <8.5; Fasting Blood Sugar <200; diagnosis of Diabetes less than 1 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; Renal Failure; Heart failure; Hemorrhagic strokes; hypothyroidism and hyperthyroidism

Age

From **20 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

Jundishapur University of Medical Sciences, Golestan Blvd

City

ahvaz

Postal code

Approval date

2014-01-11, 1392/10/21

Ethics committee reference number

ajums.REC.1392.285

Health conditions studied

1

Description of health condition studied

Type 2 Diabetes

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description

Fasting Blood Sugar

Timepoint

baseline, after six weeks

Method of measurement

Blood samples from patients, mg/dl

2

Description

2hpp (2 hour post prandial) blood glucose

Timepoint

baseline , after six weeks

Method of measurement

Blood samples from patients, mg/dl

3

Description

Fructosamine

Timepoint

baseline, after six weeks

Method of measurement

Blood samples from patients ,umol

Secondary outcomes

1

Description

Lipid profile

Timepoint

baseline, after six weeks

Method of measurement

Blood samples from patients, mg /dl

2

Description

Blood pressure

Timepoint

baseline , after six weeks

Method of measurement

Manometer, mmHg

3

Description

Body Mass Index

Timepoint

baseline, after six weeks

Method of measurement

calculated as weight (kg)/height (m2)

Intervention groups

1

Description

Forty-two Patients in addition to previous medications, Berberis vulgaris root extract Capsule 500 mg twice per day, every twelve hours for six weeks.

Category

Treatment - Drugs

2

Description

Forty-two Patients in addition to previous medications, placebo Capsule 500 mg twice per day, every twelve hours for six weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabetes Clinic Department ,Golestan Hospital

Full name of responsible person

Dr.mehrnoosh zakerkish

Street address

Golestan Hospital Farvardin St,Golestan Blvd,

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz JundishapurUniversity of Medical Sciences

Full name of responsible person

Dr.Nader saki

Street address

Deputy of Research, Ahvaz Jundishapur University of Medical Sciences

City

Ahvaz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahvaz JundishapurUniversity 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

Dr. Foroogh Namjooyan

Position

Ph.D, Assistant 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