

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

Effect of black hawthorn supplements on serum glucose, lipid profile, insulin resistance in patients with type 2 diabetes

Protocol summary

Summary

The aim of this study is survey effect of black hawthorn supplements on serum glucose, lipid profile, insulin resistance in patients with type 2 diabetes. Inclusion criteria: willingness to cooperate, the risk of type 2 diabetes, not using insulin; BMI higher than 18.5. Exclusion criteria change the type and dose of drugs. The study population are 46 patients with type 2 diabetes. Patients in the intervention group receive Black hawthorn supplement and intervention group received placebo for 8 weeks daily. At the beginning and end of the study, serum glucose and total cholesterol will be measured.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015101124473N1**

Registration date: **2016-02-05, 1394/11/16**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-02-05, 1394/11/16

Registrant information

Name

Leila Abedi Firizjai

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 3243 3681

Email address

abedi.l@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2015-10-23, 1394/08/01

Expected recruitment end date

2015-11-01, 1394/08/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of black hawthorn supplements on serum glucose, lipid profile, insulin resistance in patients with type 2 diabetes

Public title

Effect of black hawthorn supplements on serum glucose, lipid profile, insulin resistance in patients with type 2 diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: willingness to cooperate; the risk of type 2 diabetes; not using insulin; BMI higher than 18.5. Exclusion criterion: change the type and dose of drugs.

Age

From **30 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **46**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ahvaz Jundishapur University of Medical Sciences

Street address

Ahvaz

City

Ahvaz, Ahvaz Jundishapur University of Medical Sciences

Postal code**Approval date**

2015-08-07, 1394/05/16

Ethics committee reference number

IR.AJUMS.REC.1394.362

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

Type 2 diabetes

ICD-10 code

E10-14

ICD-10 code description

Diabetes mellitus

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

Cholesterol

Timepoint

Before the intervention, after intervention

Method of measurement

Enzymatic method using kits

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

Glucose

Timepoint

Before the intervention, after intervention

Method of measurement

Enzymatic method using kits

Intervention groups**1****Description**

Intervention group: black hawthorn supplement, 2 capsules of 400 mg, 2 times a day, for 8 weeks

Category

Treatment - Drugs

2**Description**

control group: placebo, 2 capsules containing avicel powder, 2 times a day, for 8 weeks

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Babol Rohani Hospital

Full name of responsible person

Leila Abedi

Street address

Rohani Hospital, Babol, Mazandaran, IRAN

City

Babol

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Ahvaz Jundishapur University of Medical Sciences Vice Chancellor for Research and Technology Developm

Full name of responsible person

Leila Abedi

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Rohani Hospital, Babol, Mazandaran, IRAN

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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

Ahvaz Jundishapur University of Medical Sciences Vice Chancellor for Research and Technology Developm

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***City**

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Full name of responsible person

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Position

Masters student

Other areas of specialty/work**Street address**

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Fax**Email****Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Dr. Durdana Hosin

Position

PhD Nutrition

Other areas of specialty/work**Street address**Ahvaz Jundishapur University of Medical Sciences,
Ahvaz, Khozestan, Iran**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*