

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of hydroalcoholic extract of Morus alba on glucose and lipid profiles in patient with diabetes mellitus type 1

Protocol summary

Summary

This study will be a double blind and cross over clinical trial on 30 patients 10 to 30 years of age, taking insulin with type 1 diabetes for one year. Patients with liver or kidney disease or low levels of lipid profile will be excluded. At the baseline, insulin intake rate, area under the curve of blood glucose at different times in the past week, fasting blood glucose and HbA1C, triglycerides, total cholesterol, LDL- cholesterol, serum HDL cholesterol, CRP and ALT and AST will be recorded for subjects. Besides their previous therapy, subjects will receive 60 placebo or capsules containing morus alba leaf extract for a month prepared by Barij Essence Company. Volunteers will be visited for a month and 2 months wash out .At the end of 1, 3 and 4 months testing and initial evaluation will be repeated and changes will be investigated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015030812438N11**

Registration date: **2015-04-19, 1394/01/30**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-04-19, 1394/01/30

Registrant information

Name

Mohsen Taghizadeh

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Barij Essence pharmaceutical company

Expected recruitment start date

2015-04-21, 1394/02/01

Expected recruitment end date

2015-12-22, 1394/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of hydroalcoholic extract of Morus alba on glucose and lipid profiles in patient with diabetes mellitus type 1

Public title

Effect of Morus alba on diabetes mellitus type 1

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients 10 to 30 years who have insulin-dependent diabetes disease and HbA1c in his with more than 7 percent. Exclusion criteria: LDL cholesterol and triglycerides less than 160 and less than 200 respectively. Liver disease, kidney disease, not use of lipid-lowering drugs.

Age

From **10 years** old to **30 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 30

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kashan University of Medical Sciences

Street address

Kashan University Of Medical Sciences, Kashan

City

Kashan

Postal code

Approval date

2015-02-10, 1393/11/21

Ethics committee reference number

29/5/1/5347/پ

Health conditions studied

1

Description of health condition studied

Insulin-dependent diabetes mellitus

ICD-10 code

E10

ICD-10 code description

Insulin-dependent diabetes mellitus

Primary outcomes

1

Description

HbA1C

Timepoint

months 0,2,4,6

Method of measurement

percent of glycosylated hemoglobin

2

Description

Fasting plasma glucose

Timepoint

months 0,2,4,6

Method of measurement

Enzymatic

3

Description

Tg

Timepoint

months 0,2,4,6

Method of measurement

blood sample

4

Description

cholesterol

Timepoint

months 0,2,4,6

Method of measurement

blood sample

5

Description

LDL

Timepoint

months 0,2,4,6

Method of measurement

blood sample

6

Description

HDL

Timepoint

months 0,2,4,6

Method of measurement

blood sample

7

Description

CRP

Timepoint

months 0,2,4,6

Method of measurement

blood sample

8

Description

ALT,AST

Timepoint

months 0,2,4,6

Method of measurement

blood sample

Secondary outcomes

1

Description

taking insulin

Timepoint

months 0,2,4,6

Method of measurement

questionnaire

Intervention groups

1

Description

intervention:herbal capsule BID, for 3 months+ routine treatment

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

office

Full name of responsible person

Street address

City

Kashan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Barij Research Center of Medicinal Herbs

Full name of responsible person

Miss L.Hejazi

Street address

Kashan Mashhad Ardehal Road, KM44

City

Kashan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Barij Research Center of Medicinal Herbs

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

Kashan University of Medical Sciences

Full name of responsible person

Dr.M.Taghizadeh

Position

PHD

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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Name of organization / entity

Barij Research Center of Medicinal Herbs

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M.Mahlouji

Position

Clinical Expert

Other areas of specialty/work

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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