# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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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+98 36 1555 0021

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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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**Full name of responsible person**
Dr Kobra Shiasi
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Pediatric Endocrinology and Metabolism
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## Person responsible for updating data

**Contact**
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Barij Research Center of Medicinal Herbs
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Clinical Expert
**Other areas of specialty/work**
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**Phone**

00

**Fax**

**Email**

mahnaz.mahlouji@yahoo.commahnaz.mahlouji@gmail.com

**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*