

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 2026

### A clinical trial the effect of hydroalcoholic extracts of Morus Alba leaves capsules on nephropathic complications of diabetic patients type 2

#### Protocol summary

2016-06-08, 1395/03/19

#### Summary

This study investigated the effect of capsule containing alcoholic extract of Morus Alba leaves on complications of diabetic nephropathy in patients with type II based on a double-blind, parallel clinical trial on 70 patients 35 to 70 years of age receiving dietary advice and hypoglycemia tablets for 3-5 years suffering from diabetic nephropathy. Low density lipoprotein and triglycerides should be less than 130 and 300 respectively. Patients with liver disease and changes in dose excluded. insulin levels, fasting blood glucose, HbA1C, triglycerides, total cholesterol, LDL- cholesterol, HDL- cholesterol, TAC, BUN, Creatinin, pro, ALT , AST ,24 recall receiving food will be recorded for candidates at the beginning of study. Volunteers were randomly divided into two groups according to the table of random numbers and besides their previous treatment will receive 120 capsules containing Morus Alba leaf extract or a placebo capsule which has been prepared by Barij essence pharmaceutical company. In order to blind, drug and placebo were prepared in the same packaging and coded in formulation department of Barij Essence Company. Drug and placebo code will be decoded and analyzed at the end of the study. Volunteers will be visited monthly and preliminary testing and re-done and changes will be examined at the end of second months.

#### Registrant information

##### Name

Mohsen Taghizadeh

##### Name of organization / entity

Kashan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

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##### Email address

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#### Recruitment status

##### Recruitment complete

#### Funding source

Barij Research Center of Medicinal Plants

#### Expected recruitment start date

2016-04-03, 1395/01/15

#### Expected recruitment end date

2017-04-04, 1396/01/15

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016021512438N18**

Registration date: **2016-06-08, 1395/03/19**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

#### Scientific title

A clinical trial the effect of hydroalcoholic extracts of Morus Alba leaves capsules on nephropathic complications of diabetic patients type 2

#### Public title

The effect of capsular extract of Morus Alba leaves on nephropathic complications of diabetes mellitus type 2

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

inclusion criteria: patients 35 to 70 years old receiving

reducer blood glucose drug and dietary recommendations for 3 to 5 years with type II diabetes. That LDL-cholesterol less than 130 and triglycerides less than 300. Exclusion criteria: liver disease, allergies to plants used in the clinical trial, changing the dose of drug during the study.

#### **Age**

From **35 years** old to **70 years** old

#### **Gender**

Both

#### **Phase**

2

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **70**

#### **Randomization (investigator's opinion)**

Randomized

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Double blinded

#### **Blinding description**

#### **Placebo**

Used

#### **Assignment**

Parallel

#### **Other design features**

Randomized based on table of random numbers

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Ethics committee of Kashan University of Medical Sciences

##### **Street address**

Kashan University Of Medical Sciences, Kashan

##### **City**

Kashan

##### **Postal code**

#### **Approval date**

2016-02-03, 1394/11/14

#### **Ethics committee reference number**

IR.KAUMS.REC.1394.147

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Diabetic Nephropathy

#### **ICD-10 code**

E11.2

#### **ICD-10 code description**

Non-insulin-dependent diabetes mellitus with renal

complications

## **Primary outcomes**

### 1

#### **Description**

Fasting plasma glucose

#### **Timepoint**

Baseline and End-of-tria

#### **Method of measurement**

blood sample

### 2

#### **Description**

lipid profile

#### **Timepoint**

Baseline and End-of-tria

#### **Method of measurement**

blood sample

### 3

#### **Description**

insulin

#### **Timepoint**

Baseline and End-of-tria

#### **Method of measurement**

blood sample

### 4

#### **Description**

Total anti oxidant capacity(TAC)

#### **Timepoint**

Baseline and End-of-tria

#### **Method of measurement**

blood sample

### 5

#### **Description**

alanine aminotransferase(ALT), Aspartate aminotransferase(AST)

#### **Timepoint**

Baseline and End-of-tria

#### **Method of measurement**

blood sample

### 6

#### **Description**

Hs-CRP

#### **Timepoint**

Baseline and End-of-tria

#### **Method of measurement**

blood sample

### 7

#### **Description**

Blood urea nitrogen

## Timepoint

Baseline and End-of-tria

## Method of measurement

urine sample

## 8

### Description

CREATININ

### Timepoint

Baseline and End-of-tria

### Method of measurement

urine sample

## 9

### Description

PRO

### Timepoint

Baseline and End-of-tria

### Method of measurement

urine sample

## 10

### Description

HbA1C

### Timepoint

Baseline and End-of-tria

### Method of measurement

percent of glycosylated hemoglobin

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

control group: routine treatment+ placebo cap BID, 2 months

#### Category

Placebo

### 2

#### Description

intervention group: routine treatment+ extract of Morus Alba leaves cap BID,2 months

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Kashan diabetes center

##### Full name of responsible person

Dr Mohsen Taghizadeh

## 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

#### 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*

### 2

#### Sponsor

##### Name of organization / entity

Vice chancellor for research of Kashan University of Medical Science

##### Full name of responsible person

Dr Gholam Ali Hamidi

##### Street address

Kashan university of Medical Science, Kashan

##### City

Kashan

#### 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 of Kashan University of Medical Science

#### Proportion provided by this source

#### 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*

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## Person responsible for general inquiries

### Contact

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## Person responsible for scientific inquiries

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## Person responsible for updating data

### Contact

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Barij Research Center of Medicinal Herbs  
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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*