Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

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

Protocol summary

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.

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

2016-06-08, 1395/03/19

Registrant information

Name
Mohsen Taghizadeh

Name of organization / entity
Kashan University of Medical Sciences

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Iran (Islamic Republic of)

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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

Scientific title
A clinical trial the effect of hydroalcoholicl 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

Person responsible for general inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Dr.Mohsen Taghizadeh

Position

PHD

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