

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The effect of hydroalcoholic capsular extract of Blueberry on nephropathic complications of diabetes mellitus type 2

Protocol summary

Summary

This study is a double-blind, parallel clinical trial on 70 patients 35 to 70 years of age taking dietary advice and medicine that reduce blood sugar. Patient that 3-5 years old with diabetic nephropathy type II. HbA1c of 7-9%, LDL cholesterol and triglycerides less than 300 and less than 130 and with 0 and 1 grades of nephropathy. Patients with liver disease and end stage of nephropathy excluded. At baseline insulin levels, fasting blood glucose, HbA1C, triglycerides, total cholesterol, LDL-cholesterol, HDL-cholesterol, TAC, ALT and, BUN, creatinin, pro ,AST ,24 recall receiving food will be recorded for subjects. In addition to their previous therapy, subjects will receive 60 placebo capsules or capsule containing blueberry extract for a month prepared by Barij Essence company. Volunteers will be visited monthly and if there is no problem they will receive it again for a months. At the end of 3 months testing and initial evaluation will be repeated and changes will be investigated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015040712438N12**

Registration date: **2015-05-26, 1394/03/05**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-05-26, 1394/03/05

Registrant information

Name

Mohsen Taghizadeh

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

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taghizadeh_m@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Barij essence pharmaceutical company

Expected recruitment start date

2015-06-22, 1394/04/01

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 capsular extract of Blueberry on nephropathic complications of diabetes mellitus type 2

Public title

Effect of blueberry on type 2 Diabetic Nephropathy

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 HbA1c is 9-7%. LDL-cholesterol less than 130 and triglycerides less than 300. with 0 and 1Stage of diabetic nephropathy that do not use fat-lowering drugs. 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

1-2

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

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

29/5/1/5349/پ

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

HbA1C

Timepoint

Baseline and End-of-trial

Method of measurement

percent of glycosylated hemoglobin

2

Description

Insulin

Timepoint

Baseline and End-of-trial

Method of measurement

blood sample

3

Description

lipid profile

Timepoint

Baseline and End-of-trial

Method of measurement

blood sample

4

Description

Fasting plasma glucose

Timepoint

Baseline and End-of-trial

Method of measurement

blood sample

5

Description

TAC

Timepoint

Baseline and End-of-trial

Method of measurement

blood sample

6

Description

ALT,AST

Timepoint

Baseline and End-of-trial

Method of measurement

blood sample

7

Description

BUN

Timepoint

Baseline and End-of-trial

Method of measurement

urine sample

8

Description

creatinin

Timepoint

Baseline and End-of-trial

Method of measurement

urine sample

9**Description**

PRO

Timepoint

Baseline and End-of-trial

Method of measurement

urine sample

Secondary outcomes

empty

Intervention groups**1****Description**intervention group:routine treatment+blueberry cap
BID,3 months**Category**

Treatment - Drugs

2**Description**control group:routine treatment+placebo cap BID,3
months**Category**

Placebo

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

Dialysis Center of Beheshti hospital

Full name of responsible person**Street address****City**

Kashan

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

Barij Essence Company

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 Essence Company

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**Street address**

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Full name of responsible person

Dr Mohsen Taghizadeh

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Person responsible for updating data

Contact

Name of organization / entity

Barij Research Center of Medicinal Herbs

Full name of responsible person

M.Mahlouji

Position

Clinical Expert

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

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00

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mahnaz.mahlouji@yahoo.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