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)

Phone

+98 36 1555 0021

Email address

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
Kashan University Of Medical Sciences, Kashan
City
Kashan
Postal code
Phone
+98 31 5554 0021
Fax
Email
taghizadeh_m@kaums.ac.ir
Web page address

Person responsible for scientific 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
Street address
Kashan University Of Medical Sciences, Kashan
City
Kashan
Postal code
Phone
+98 31 5554 0021
Fax
Email
taghizadeh_m@kaums.ac.ir
Web page address

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
Kashan Mashhad Ardehal Road, KM44

City

Postal code

Phone
00

Fax

Email
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