

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Double-blind clinical study of the therapeutic effects of pomegranate juice powder on renal damage in diabetic nephropathy.

Protocol summary

Summary

This study is a double-blind, parallel clinical trial on 40 patients 20 to 75 years of age taking dietary advice and medicine that reduce blood sugar. Patient's urine microalbumin and the amount of protein in urine 24 hours higher than normal and receive a fixed dose of either or both ACEI or ARB at least 3 months. Patients with underlying diseases such as cancer, as well as being on dialysis excluded. At baseline Fasting Blood Sugar, Serum BUN, Serum Cr, Triglycerides, Total Cholesterol, LDL- cholesterol, HDL- cholesterol, ALT, AST, Urine microalbumin and Urine protein 24 hours will be recorded for subjects. In addition to their previous therapy, subjects will receive 120 placebo capsules or capsule containing pomegranate juice powder for a month. Volunteers will be visited monthly and if there is no problem they will receive it again for a month. At the end of 2 months testing and initial evaluation will be repeated and changes will be investigated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015121725574N1**

Registration date: **2016-05-31, 1395/03/11**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-05-31, 1395/03/11

Registrant information

Name

Elnaz Faridi

Name of organization / entity

Motahari Clinic

Country

Iran (Islamic Republic of)

Phone

+98 71 3227 0295

Email address

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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2016-02-29, 1394/12/10

Expected recruitment end date

2016-12-30, 1395/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Double-blind clinical study of the therapeutic effects of pomegranate juice powder on renal damage in diabetic nephropathy.

Public title

The effect of pomegranate juice powder on diabetic nephropathy

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: patients 20 to 75 years old receiving reducer blood glucose drug and dietary recommendations for at least 6 month with type II diabetes. That the urine microalbumin and the amount of protein in urine 24 hours higher than normal and receive a fixed dose of either or both ACEI or ARB at least 3 months. Exclusion criteria: certain underlying diseases such as autoimmune diseases or cancer, allergies to

plants used in the clinical trial, pregnancy and breastfeeding, dialysis.

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **40**

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

Shiraz University of Medical Sciences

Street address

Central Building of Shiraz University of Medical Science, Zand Street, Shiraz

City

Shiraz

Postal code

Approval date

2015-08-01, 1394/05/10

Ethics committee reference number

IR.Sums.REC.1394.132

Health conditions studied

1

Description of health condition studied

Nephropathy caused by diabetes type 2

ICD-10 code

E10-E14

ICD-10 code description

Diabetes mellitus With renal complications Diabetic nephropathy (N08.3*)

Primary outcomes

1

Description

The 24-hour urine protein excretion

Timepoint

Before the intervention, one month after the intervention and after the end of the intervention

Method of measurement

24-hour urine test

2

Description

Urine microalbumin excretion

Timepoint

Before the intervention, one month after the intervention and after the end of the intervention.

Method of measurement

urine test

Secondary outcomes

1

Description

Serum BUN

Timepoint

The beginning and end of the intervention

Method of measurement

blood tests

2

Description

Serum Creatinine

Timepoint

The beginning and end of the intervention

Method of measurement

blood tests

3

Description

Fasting Blood Sugar

Timepoint

The beginning and end of the intervention

Method of measurement

blood tests

4

Description

BMI

Timepoint

The beginning and end of the intervention

Method of measurement

blood tests

5

Description

GFR

Timepoint

The beginning and end of the intervention
Method of measurement
blood tests

6

Description

HDL

Timepoint

The beginning and end of the intervention

Method of measurement

blood tests

7

Description

LDL

Timepoint

The beginning and end of the intervention

Method of measurement

blood tests

8

Description

Cholesterol

Timepoint

The beginning and end of the intervention

Method of measurement

blood tests

9

Description

TG

Timepoint

The beginning and end of the intervention

Method of measurement

blood tests

Intervention groups

1

Description

intervention group:routine treatment+blueberry cap
qID,2 months

Category

Treatment - Drugs

2

Description

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

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Motahari clinic

Full name of responsible person

Elnaz Faridi

Street address

Motahari Clinic, Namazi Square, Shiraz

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Pouya Faridi

Street address

Shiraz University of Medical Sciences, front of the
Felestin street, Zand Avenue, Shiraz.

City

Shiraz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shiraz University of Medical Sciences

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

Shiraz University of Medical Sciences

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Assistant Professor

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