Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 proteine 24houres 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 months. 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
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Name of organization / entity
Motahhari Clinic

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Iran (Islamic Republic of)

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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
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Motahari Clinic, Namazi Square, Shiraz
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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
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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