

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

A study comparing the effectiveness of pomegranate versus Gabapentin for treatment of Diabetic nephropathy in patients of diabetes melitus type 2

Protocol summary

Study aim

A study comparing the effectiveness of pomegranate versus Gabapentin for treatment of Diabetic nephropathy in patients of diabetes melitus type 2

Design

This study is clinical trial and double blind. A total of 74 patients with diabetes type 2 will be enrolled in Amiralmomenin hospital in Arak. We will divide patients in 2 groups by simple randomization. Groups are parallel.

Settings and conduct

This study is clinical trial and double blind. A total of 74 patients with diabetes type 2 will be enrolled in Amiralmomenin hospital in Arak. Outcome assessor and analyzer don't aware from grouping.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with type 2 diabetes who have painful lower extremity nephropathy for at least 3 months, age between 70 and 30 years, do not take pomegranate pills, do not have severe physical, neurological or psychiatric illness, do not become pregnant or breast-feeding, Exclusion criteria: Severe sensitivity to pomegranate pills, severe grade 4 heart failure or unstable angina, HbA1c greater than or equal to 8.5

Intervention groups

In the pomegranate medicine group, patients are given pomegranate tablet (225 milligram - Amin.Co Iran) half pills every 12 hours for 3 months. Patients in Gabapentin group were also given a 300 milligram tablet every 8 hours for 3 months.

Main outcome variables

Lower extremity nephropathy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020258N137**

Registration date: **2020-03-15, 1398/12/25**

Registration timing: **retrospective**

Last update: **2020-03-15, 1398/12/25**

Update count: **0**

Registration date

2020-03-15, 1398/12/25

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 3222 2003

Email address

f.farokhi@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2013-08-01, 1392/05/10

Expected recruitment end date

2015-12-31, 1394/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A study comparing the effectiveness of pomegranate

versus Gabapentin for treatment of Diabetic nephropathy in patients of diabetes melitus type 2

Public title

A study comparing the effectiveness of pomegranate versus Gabapentin for treatment of Diabetic nephropathy in patients of diabetes melitus type

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with type 2 diabetes who have painful lower extremity nephropathy for at least 3 months Age between 70 and 30 years Do not take pomegranate pills. Do not have severe physical, neurological or psychiatric illness. Do not become pregnant or breast-feeding.

Exclusion criteria:

Severe sensitivity to pomegranate pills Severe grade 4 heart failure or unstable angina HbA1c greater than or equal to 8.5

Age

From **30 years** old to **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **74**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple individual randomization with randomization with envelopes in two groups A and B. In this method, we selected a number of cards or letters as an intervention group and the same number of cards for the control group, then the cards were merged. One card was taken out and its allocation was registered and the card was returned to the other cards after leaving. Then the cards are merged again and we remove another card. This process continues to reach a random sequence according to sample size.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is double blind. Researcher who complete questionnaire and analyzer are blind (double blind). Outcome assessor and analyzer don't aware from grouping. The person evaluating the outcome is unaware of the grouping. Groups A and B are available to analyzer and outcome assessor.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

Ethics committee, Research center, Payambar Azam complex, Basij square, Sardasht, Arak

City

Arak

Province

Markazi

Postal code

3848176941

Approval date

2013-07-31, 1392/05/09

Ethics committee reference number

92-150-4

Health conditions studied

1

Description of health condition studied

Type 2 diabetes

ICD-10 code

E08

ICD-10 code description

Diabetes mellitus due to underlying condition

Primary outcomes

1

Description

Lower extremity nephropathy

Timepoint

Start and 3 months after intervention

Method of measurement

Examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the pomegranate medicine group, patients are given pomegranate tablet (225 milligram - Amin.Co Iran) half pills every 12 hours for 3 months.

Category

Treatment - Drugs

2

Description

Intervention group: Patients in Gabapentin group were also given a 300 milligram tablet every 8 hours for 3 months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amiralmomenin Hospital

Full name of responsible person

Dr Javad Tabaeyan

Street address

Sardasht, Basij square, Amiralmomenin hospital

City

Arak

Province

Markazi

Postal code

3848176941

Phone

+98 86 3222 2003

Fax

+98 86 3222 2003

Email

tabaeean@arakmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Mohammad Arjmandzadegan

Street address

Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak

City

Arak

Province

Markazi

Postal code

3848176941

Phone

+98 86 3222 2003

Fax

+98 86 3222 2003

Email

arjmandzadegan@arakmu.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Arak University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries

Contact**Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Dr Javad Tabaeyan

Position

Assistant

Latest degree

Specialist

Other areas of specialty/work

Neurology

Street address

Valiasr hospital, Valiasr square, Shahid Shirodi street, Arak

City

Arak

Province

Markazi

Postal code

3814957558

Phone

+98 634173638

Fax

+98 86 3222 2003

Email

Tabaeean@arakmu.ac.ir

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Arak University of Medical Sciences

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Person responsible for updating data

Contact

Name of organization / entity
Arak University of Medical Sciences
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Assistant
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Arak
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Fax
+98 86 3222 2003
Email
Tabaeean@arakmu.ac.ir
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

When we publish article in journal

When the data will become available and for how long

After the article is published

To whom data/document is available

Researcher in university

Under which criteria data/document could be used

If there are additional questions

From where data/document is obtainable

Dr Javad Tabaeean

What processes are involved for a request to access data/document

They have to write letters to the professors and the university

Comments