Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

A study comparing the effectiveness of pomegranate versus Gabapentin for treatment of Diabetic nephropathy in patients of diabetus 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

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Iran (Islamic Republic of)

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+98 86 3222 2003

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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 diabetus melitus type 2

Public title
A study comparing the effectiveness of pomegranate versus Gabapentin for treatment of Diabetic nephropathy in patients of diabetus 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 comittee of Arak University of Medical Sciences
Street address
Ethics comittee, Research center, Payambar Azam complex, Basij squre , 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 squre,Amiralmomenin hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
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Person responsible for updating data

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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