Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Evaluation of the effect of allopurinol on nephropathy in diabetic patients

Protocol summary

Study aim
The determination of the effect of allopurinol on nephropathy in diabetic patients

Design
Clinical trial with control group, parallel group, double blind, randomized

Settings and conduct
Sixty diabetic nephropathy patients with hyperuricemia referred to Nephrology Clinics of Shahrekord University of Medical Sciences were selected by convenience sampling method and randomly divided into control and control groups. The patients were then measured on the first day of 24-hour urine tests for protein, GFR estimates, and serum uric acid levels, and then assigned to one group of allopurinol patients and another to placebo. The patients were followed for 6 months. After 24-hour urine collection follow-up, the protein was measured, GFR estimates and serum uric acid levels were compared, and the results were compared between the two groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 24-hour urine protein greater than 150mg / dl; Uric acid between 6 and 15; Informed patient satisfaction; The severity of diabetic nephropathy is similar in both groups; Passive urine sedimentation; Exclusion criteria: Patients treated with allopurinol; Patients with significant renal failure (Cr> 3 mg / dl) or (GFR <25cc / min)

Intervention groups
We have two case and control groups. One group of patients was given allopurinol and the other group was given placebo

Main outcome variables
Serum uric acid level, glomerular filtration rate, 24 hour urine protein, serum creatinine level, serum urea level

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200117046158N1**
Registration date: **2020-03-14, 1398/12/24**
Registration timing: **registered_while_recruiting**

Last update: **2020-03-14, 1398/12/24**
Update count: **0**

Registration date
2020-03-14, 1398/12/24

Registrant information

Name
Farzaneh Kadkhodaei Elyaderani

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 38 3222 0016

Email address
farzanehmedical@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-02-14, 1398/11/25

Expected recruitment end date
2020-08-15, 1399/05/25

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effect of allopurinol on nephropathy in diabetic patients

Public title
Effect of allopurinol on diabetic nephropathy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

24-hour urine protein greater than 150mg / dl Uric acid between 6 and 15 Informed patient satisfaction The severity of diabetic nephropathy is similar in both groups Passive urine sedimentation

Exclusion criteria:

Patients treated with allopurinol Patients with significant renal failure (Cr> 3 mg / dl) or (GFR <25cc / min)

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

60 diabetic nephropathy patients who were eligible for inclusion in the study will be enrolled by the simple randomized method. Then they will be divided into two groups of 30 using the random block method with 3 blocks. Thus, the first three cases in the first group, the second three cases in the second group, the third three cases in the first group, the forth three cases in the second group and this will be continued in the same way till the ending of samples.

Blinding (investigator's opinion)

Double blinded

Blinding description

The drugs were placed in envelopes in packages A and B without labeling and without the knowledge of the investigator.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahrekord University of Medical Sciences

Street address

Vice chancellor for research, Building No. 2, University headquarters, Ayatollah Kashani Blvd

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8815713492

Approval date

2019-02-24, 1397/12/05

Ethics committee reference number

IR.SKUMS.REC.1397.303

Health conditions studied

1

Description of health condition studied

Diabetic nephropathy

ICD-10 code

E09.21

ICD-10 code description

Drug or chemical induced diabetes mellitus with diabetic nephropathy

Primary outcomes

1

Description

Serum uric acid level

Timepoint

After 3 and 6 months after starting the study

Method of measurement

Test

2

Description

GFR (Glomerular filtration rate)

Timepoint

After 3 and 6 months after starting the study

Method of measurement

Formula

3

Description

24-hour urine protein content

Timepoint

After 3 and 6 months after starting the study

Method of measurement

24-hour urine test

4

Description

Serum creatinine level

Timepoint

After 3 and 6 months after starting the study

Method of measurement

Test

5

Description
Serum urea level
Timepoint
After 3 and 6 months after starting the study
Method of measurement
Test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients in the case group are treated with allopurinol 100 mg daily
Category
Treatment - Drugs

2

Description
Control group: Patients in the control group receive one placebo daily
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Ali Clinic
Full name of responsible person
Saeed Mardani
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2

Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Dr. Mehraban Sadeghi
Street address
Vice chancellor for research, Building No. 2, University headquarters, Ayatollah Kashani Blvd
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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
Shahre-kord 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
Shahre-kord University of Medical Sciences
Full name of responsible person
Saeed Mardani
Position
Assistant Professor of Nephrology
Latest degree
Subspecialist

Other areas of specialty/work
Nephrology
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
No - There is not 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
Information about the main outcome can be shared.
When the data will become available and for how long
Start the access period 4 months after publishing the results
To whom data/document is available
Researchers working in academia
Under which criteria data/document could be used
Use data to complete clinical trial studies
From where data/document is obtainable
Imam Ali clinic and Hazrat Rasool clinic
What processes are involved for a request to access data/document
After the investigation of researcher request and presentation of required documents will be accessible.
Comments