

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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)

Phone

+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 fourth 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

Street address

Shariati Blvd., Imam Ali Clinic

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2

Recruitment center

Name of recruitment center

Hazrat Rasool Clinic

Full name of responsible person

Saeed Mardani

Street address

Molavi Street, Hazrat Rasool Clinic

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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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kamal_solati@yahoo.com

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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Nursery Street, Shahrekord

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Person responsible for scientific 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

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Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Shahre-kord University of Medical Sciences

Full name of responsible person

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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