

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Study of the effect of Allopurinol on renal residual function in hyperuricemic peritoneal dialysis patients

Protocol summary

Study aim

Aim of this study is evaluation of Allopurinol on residual renal function in peritoneal dialysis patients.

Design

A randomised, blinded clinical trial with a parallel group without placebo use.

Settings and conduct

Peritoneal dialysis patients with hyperuricemia are divided in 2 groups. According to randomized numbers, they are divided to group with drug use and group without drug use. Nurse and investigator are blinded to drug use and patients are visited by physician.

Participants/Inclusion and exclusion criteria

49 patients arrived in study. Inclusion criteria are: peritoneal dialysis at least 3 months, uric acid level more than 7mg/dL in men and more than 6mg/dL in women and residual renal function more than 2cc/min. Exclusion criteria are death, change to hemodialysis, renal transplantation, drug allergy or complication of drug.

Intervention groups

They receive tablet allopurinol 100 mg manufactured by Jalinous company for 6 months and uric acid level and residual renal function are measured at beginning and the end of study. results compare with same patient without drug therapy.

Main outcome variables

determination of residual renal function after drug use.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090905002417N20**

Registration date: **2018-03-21, 1397/01/01**

Registration timing: **retrospective**

Last update: **2018-03-21, 1397/01/01**

Update count: **0**

Registration date

2018-03-21, 1397/01/01

Registrant information

Name

Firouzeh Moeinzadeh

Name of organization / entity

Isfahan University of Medical Sciences

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Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Isfahan University of Medical Sciences

Expected recruitment start date

2017-03-21, 1396/01/01

Expected recruitment end date

2018-01-20, 1396/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the effect of Allopurinol on renal residual function in hyperuricemic peritoneal dialysis patients

Public title

Effect of Allopurinol on renal residual function

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
consent for cooperation peritoneal dialysis for at least 3 months 18-80 years old hyperuricemia: uric acid level $\geq 7\text{mg/dL}$ in men and $\geq 6\text{mg/dL}$ in women minimum residual renal function : 2cc/min/m^2

Exclusion criteria:
death allopurional allergy or complications hemodialysis rout for dialysis renal transplantation nephrotoxic drug use

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **98**

Randomization (investigator's opinion)

Randomized

Randomization description

simple randomization, table of random numbers

Blinding (investigator's opinion)

Double blinded

Blinding description

participants, nurses and investigator are blinded in this study.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Vice Chancellor for Research,
Isfahan University of Medical Sciences

Street address

Hezar jarib street, Isfahan

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2017-01-11, 1395/10/22

Ethics committee reference number

IR.MUI.REC.1395.3.837

Health conditions studied

1

Description of health condition studied

end stage renal disease

ICD-10 code

N18.0

ICD-10 code description

end stage renal disease

Primary outcomes

1

Description

serum uric acid level

Timepoint

before intervention and 6 months after drug use

Method of measurement

laboratory kit- ELISA- with HITACHI equipment

2

Description

residual renal function

Timepoint

before intervention and 6 months after drug use

Method of measurement

renal function formula

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Allopurinol tablet usage, 100mg daily orally for 6 months manufactured by Jalinous company

Category

Treatment - Drugs

2

Description

Control group: no drug use

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person
Shirin Karimi
Street address
Alzahra Hospital, Sofe Avenue, Isfahan
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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

Esfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Dr. Elham kabiri
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Internal medicine resident
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Person responsible for updating data

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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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Primary outcome measure could be shared after termination of study.

When the data will become available and for how long

starting 1 year after publication

To whom data/document is available

Academic institution can apply to receive it

Under which criteria data/document could be used

using data for similar studies

From where data/document is obtainable

get documents by e-mail address to information provider

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

After introduce and academic information, please explain your aim(s). they must committal to refer this study as reference if they use data. otherwise we entitle to follow these to Ethic committee.

Comments