

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

The effect of Allopurinol in prevention of contrast induced nephropathy in patients undergoing angioplasty

Protocol summary

Study aim

Determination of the effect of Allopurinol in preventing contrast-induced nephropathy based on GFR

Determination of the effect of Allopurinol in preventing contrast-induced nephropathy based on hyperuricemia

Design

This clinical trial is randomized, double-blinded and with control group. Randomization will be done using the Randlist software. The case group is given allopurinol at a dose of 300 mg before angiography and then 300 mg one hour before angiography is given to the patient. The control group will also use the placebo.

Settings and conduct

This study was carried out at the Shahid Madani Hospital in Tabriz and patients will receive a blood sample within 3 days after angioplasty. A urine sample will also be taken from patients for analysis and evaluation of proteinuria. Also, the patients and the practitioner who perform the treatment will be unaware of the type of treatment being prescribed. All angioplasty will be performed by an experienced cardiologist. The VISPIAQUE injection of 320mg / ml, 100ml GE HEALTHCARE (Norway), and the volume of the contrast agent based on urea and creatinine and GFR of the patients will be adjusted to a maximum of 100cc to be used.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age above 50, first anisoplasty, elective angioplasty, high creatinine dl / mg 1.1 Exclusion criteria: emergency angioplasty, diabetes, history of acute rheumatic fever, chronic renal failure, and history of kidney disease

Intervention groups

Allopurinol was used in the case group and placebo was used in the control group

Main outcome variables

The GFR and the Mehran Contrast Nephropathy Risk Score are calculated. The amount of creatinine, uric acid, calcium, magnesium, and albumin is measured.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190406043182N1**

Registration date: **2019-10-05, 1398/07/13**

Registration timing: **retrospective**

Last update: **2019-10-05, 1398/07/13**

Update count: **0**

Registration date

2019-10-05, 1398/07/13

Registrant information

Name

haleh bodagh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3389 3710

Email address

haleh.bodagh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-17, 1398/01/28

Expected recruitment end date

2019-04-24, 1398/02/04

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Allopurinol in prevention of contrast induced nephropathy in patients undergoing angioplasty

Public title

The effect of Allopurinol in prevention of contrast induced nephropathy in patients undergoing angioplasty

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

inclusion criteria: 1. Age > 55, 2. The first turn of angioplasty 3. Elective angioplasty 4. Creatinine > 1 mg / kg 5. Normal GFR Out put

Exclusion criteria:

Exclusion criteria: 1. Emergency Angioplasty, 2. Diabetes 3. History of the ARF 4. Chronic renal failure 5. Family history of kidney disease

Age

From **55 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data and Safety Monitoring Board

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Finally, 100 patients were randomly assigned to either a 50-dose or a placebo group using the Randomization Block method. Randomization is done using Excel software. Allocation concealment is fully respected.

Blinding (investigator's opinion)

Double blinded

Blinding description

When patients fill out a clinical trial consent they may receive the drug or placebo at random. Neither the patient nor the nurses are aware of the contents of the envelopes. The nurse gives these drugs to patients in pre-packages. These envelopes contain six tablets of 100 mg Allopurinol or six tablets of similar appearance (sugar and gypsum). The statistics specialist will eventually provide the relevant information to the researcher who analyzes the data.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

Street address

Golgshest St.-Tabriz University of Medical Sciences

City

tabriz

Province

East Azarbaijan

Postal code

5165665931

Approval date

2019-02-28, 1397/12/09

Ethics committee reference number

IR.TBZMED.REC.1397.959

Health conditions studied

1

Description of health condition studied

Nephropathy

ICD-10 code

28.9

ICD-10 code description

Disorder of kidney and ureter, unspecified

Primary outcomes

1

Description

GFR

Timepoint

before-after

Method of measurement

Urinary albumin level was measured by an electroanalytical analyzer, which was measured automatically by spectrophotometric method.

Secondary outcomes

empty

Intervention groups

1

Description

Use of Allopurinol

Category

Treatment - Drugs

2

Description

Use of Placebo

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Madani Hospital in Tabriz

Full name of responsible person

Nase Aslanaabadi/Haleh Bodagh

Street address

Aazadi Ave-golgasht-Tabriz University of Medical Science

City

Tabriz

Province

East Azarbaijan

Postal code

5165665931

Phone

+98 41 3335 5921

Fax

+98 41 3335 9680

Email

haleh.bodagh@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Naser Aslanaabadi/Haleh Bodagh

Street address

Aazadi ave-golgasht-Tabriz university of medical science

City

Tabriz

Province

East Azarbaijan

Postal code

5165665931

Phone

+98 41 3335 5921

Fax

+98 41 3335 9680

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Haleh Bodagh

Position

Associate

Latest degree

Specialist

Other areas of specialty/work

Cardiology

Street address

University Street, opposite to the University of R & D Complex, Shahid Madani Hospital

City

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Province

East Azarbaijan

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Phone

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haleh.bodagh@gmail.com

Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

In order to analyze this data to extract further paper

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable