

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluating the effect of Acetazolamide on the prevention of post-operative Acute Kidney Injury (AKI) following Coronary Artery Bypass Grafting (CABG) surgery

Protocol summary

Study aim

Evaluating the effect of acetazolamide on the prevention of acute kidney injury following coronary artery bypass grafting surgery

Design

This randomized controlled trial, in phase 3 on 70 patients candidates for coronary artery bypass grafting surgery who referred to Masih Daneshvari and modaress Hospital in Tehran by block randomization method divided into intervention and control groups, enrolled in the study.

Settings and conduct

Place of study; Dr Masih Daneshvari and modarres Hospitals, How to do the study; 70 patients who are candidates for coronary artery bypass grafting surgery randomly divided into intervention or control groups by block randomization method

Participants/Inclusion and exclusion criteria

Inclusion criteria; Patients who refer to Masih Daneshvari and Modaress Hospital for coronary artery bypass grafting surgery (CABG) Exclusion criteria; Any allergies to any of the compounds in acetazolamide tablet and sulfonamide compounds Liver failure (stage II, III or liver enzymes more than 3 times) Chronic renal failure (Stage IV & V), clearance creatinine less than 30 ml / min, and anorexia Chronic heart failure (Ejection Fraction <30) Emergency CABG Hypokalemia (potassium less than 3.3 mmol / L), hyponatremia (sodium less than 135 mmol / L) Gout attack

Intervention groups

Drug group; Patients receive 500 mg acetazolamide orally on the morning of surgery Control group; This group does not receive acetazolamide.

Main outcome variables

Incidence of acute kidney injury, Increasing of Creatinine biomarker and urine output

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151227025726N21**

Registration date: **2020-09-17, 1399/06/27**

Registration timing: **registered_while_recruiting**

Last update: **2020-09-17, 1399/06/27**

Update count: **0**

Registration date

2020-09-17, 1399/06/27

Registrant information

Name

Farzaneh Dastan

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 912 270 5933

Email address

f_dastan@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-19, 1398/12/29

Expected recruitment end date

2020-10-21, 1399/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effect of Acetazolamide on the prevention of post-operative Acute Kidney Injury (AKI) following Coronary Artery Bypass Grafting (CABG) surgery

Public title

Evaluating the effect of Acetazolamide on the prevention of post-operative Acute Kidney Injury following Coronary Artery Bypass Grafting surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

It will be performed on patients who refer to Masih Daneshvari and Modares Hospital for Coronary Artery Bypass Surgery (CABG).

Exclusion criteria:

History of any allergies to any of the compounds in acetazolamide tablets and sulfonamide compounds Liver failure (stage II, III or liver enzymes more than 3 times) Chronic renal failure (Stage IV & V CKD) or patients with serum creatinine less than 30 ml / min, anorexia Chronic heart failure (Ejection Fraction <30) Patients undergoing CABG surgery for emergency reasons. Hypokalemia (potassium less than 3.3 mmol / L), hyponatremia (sodium less than 135 mmol / L) Gout attack

Age

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

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization method was used in this study by online website;(www.sealedenvelope.com/simple-randomiser/v1/lists). Fourteen blocks including 5 patients generated with this online website. In each block, patients will be assigned to acetazolamide or control group.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Beheshti University of Medical Sciences ,Pharmacy Faculty

Street address

No. 2660, Vali-e Asr St., Niyayesh Junction, Tehran

City

Tehran

Province

Tehran

Postal code

141556153

Approval date

2020-07-25, 1399/05/04

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1399.146

Health conditions studied

1

Description of health condition studied

Acute kidney injury

ICD-10 code

N99.9

ICD-10 code description

Acute kidney injury

Primary outcomes

1

Description

Creatinine plasma LEVEL

Timepoint

Before surgery and daily for up to seven days

Method of measurement

ELISA

2

Description

Volume of urine

Timepoint

Before the operation until the patient is in the intensive care unit

Method of measurement

The amount of urine in the urine bag

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in the acetazolamide group are treated with acetazolamide at a dose of 500 mg once daily on the morning of surgery.

Category

Treatment - Drugs

2

Description

Control group: Patients in the control group receive routine treatment on the day of surgery.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Masih Daneshvari Hospital

Full name of responsible person

Farzaneh Dastan

Street address

Dr. Masih Daneshvari Hospital, Daar-Abad, Niavaran

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Nima Naderi

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Vali_e Asr Ave., Niayesh junction

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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

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Golnaz Afzal

Position

Resident of Clinical pharmacy

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

Contact

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Shahid Beheshti University of Medical Sciences

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Position

Clinical Pharmacy (Pharmacotherapy) specialist, assistant professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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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

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

All of the information and knowledge achieved from this clinical trial will be published as an article

When the data will become available and for how long

About 6 months after publication of the results.

To whom data/document is available

All of people have access to the information.

Under which criteria data/document could be used

In order to use the same drug for the specific indication in the clinical wards or to use the data for designing another relevant study

From where data/document is obtainable

The information are accessible via e-mail address and phone number: golnaz afzal, afzalgolnaz95@gmail.com

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

After the end of trial, the information will be sent for a journal as a manuscript. the manuscript will be reviewed and after that, it will be published as a paper if the journal accepts the manuscript.

Comments