

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Withholding vs Maintaining aspirin prior to coronary artery bypass graft surgery; A Clinical Trial Study

Protocol summary

Study aim

Withholding vs Maintaining aspirin prior to coronary artery bypass graft surgery; a Clinical Trial Study

Design

The double blind randomized clinical trial, consisted of 204 patients who are randomly divided into 2 groups. The groups are parallel. The trial phase is 3.

Settings and conduct

The study population are patients with coronary artery bypass graft surgery, attending Amiralmomenin hospital in Arak who are divided into 4 groups by simple randomization using envelopes. The study is double-blind in which outcome evaluator, data analyst and participant are kept blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: all patients who die during surgery, all patients who come to the operating room for the first time for coronary artery bypass graft, all patients undergoing open heart surgery by a surgeon, all patients are brought to the operating room electively Exclusion criteria: patients who develop cardiac and respiratory arrest during surgery, all patients who die during surgery

Intervention groups

In the first group, aspirin will continue until the day of surgery, and in the second group, it will be stopped 48 hours before the operation.

Main outcome variables

Bleeding, mean number of postoperative FFP, mean postoperative cardiac tamponade, mean postoperative myocardial infarction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020258N150**

Registration date: **2020-10-31, 1399/08/10**

Registration timing: **registered_while_recruiting**

Last update: **2020-10-31, 1399/08/10**

Update count: **0**

Registration date

2020-10-31, 1399/08/10

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 86 3222 2003

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f.farokhi@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-21, 1397/09/30

Expected recruitment end date

2020-12-20, 1399/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Withholding vs Maintaining aspirin prior to coronary artery bypass graft surgery; A Clinical Trial Study

Public title

Withholding vs Maintaining aspirin prior to coronary artery bypass graft surgery; A Clinical Trial Study

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patients who die during surgery All patients who come to the operating room for the first time for coronary artery bypass graft All patients undergoing open heart surgery by a surgeon All patients are brought to the operating room electively

Exclusion criteria:

Patients who develop cardiac and respiratory arrest during surgery All patients who die during surgery

Age

From **35 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **204**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple individual randomization with random allocation with envelopes in 2 groups A and B . In this method, we selected a number of cards or letters as an intervention group and the same number of cards for the control group, then the cards were merged. One card was taken out and its allocation was registered and the card was returned to the other cards after leaving. Then the cards are merged again and we remove another card. This process continues to reach a random sequence according to sample size.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is clinical trial.Outcome evaluator and analyzer and participant are blind (double blind).Outcome evaluator and analyzer and participant don't aware from grouping.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Arak University of Medical Sciences

Street address

Ethics committee, Research center, Payambar Azam

complex, Basij square ,Sardasht,Arak

City

Arak

Province

Markazi

Postal code

3848176941

Approval date

2018-12-12, 1397/09/21

Ethics committee reference number

IR.ARAKMU.REC.1397.209

Health conditions studied**1****Description of health condition studied**

Coronary artery bypass graft surgery

ICD-10 code

I25.700

ICD-10 code description

Atherosclerosis of coronary artery bypass graft(s), unspecified, with unstable angina pectoris

Primary outcomes**1****Description**

Bleeding

Timepoint

During operation

Method of measurement

Observation

2**Description**

Mean number of postoperative FFP

Timepoint

After surgery

Method of measurement

Observation

3**Description**

Mean postoperative cardiac tamponade

Timepoint

After surgery

Method of measurement

Observation

4**Description**

Mean postoperative myocardial infarction

Timepoint

After surgery

Method of measurement

Observation

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the first group, aspirin will continue until the day of surgery.

Category

Treatment - Drugs

2

Description

Intervention group: In the second group, it will be stopped 48 hours before the operation.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amiralmomenin hospital

Full name of responsible person

Dr Alireza Kamali

Street address

Amiralmomenin hospital, Sardasht, Arak

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

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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

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Dr Alireza rostami

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Cardiology

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Person responsible for updating data

Contact

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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

When we publish article in journal

When the data will become available and for how long

After the article is published

To whom data/document is available

researcher in university

Under which criteria data/document could be used

If there are additional questions

From where data/document is obtainable

Dr Kamali

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

They have to write letters to the professors and the university.

Comments