Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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)
Phone
+98 86 3222 2003
Email address
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 elevator and analyzer and participant are blind (double blind).Outcome elevator 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 comittee of Arak University of Medical Sciences

Street address
Ethics comittee, Research center, Payambar Azam complex, Basij squre ,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
City
Arak
Province
Markazi
Postal code
3848176941
Phone
+98 86 3222 2003
Email
alikamaliir@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr Mohammad Arjmandzadegan
Street address
Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak
City
Arak
Province
Markazi
Postal code
3848176941
Phone
+98 86 3222 2003
Fax
+98 86 3222 2003
Email
arjmandzadegan@arakmu.ac.ir
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
Street address
Amiralmomenin hospital, Sardasht
City
Arak
Province
Markazi
Postal code
3814957558
Phone
+98 86 3222 2003
Fax
+98 86 3222 2003
Email
alikamaliir@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr Alireza Kamali
Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Valiasr Hospital, Valiasr squre, Shahid Shirodi street

City

Arak

Province

Markazi

Postal code

3814957558

Phone

+98 68 3222 2003

Fax

+98 86 3222 2003

Email

alikamaliir@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Fatemeh Fallahi

Position

medicine student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

Vice chancellor for research, Payambar Azam Complex, Basij square, Sardasht, Arak

City

Arak

Province

Markazi

Postal code

3814957558

Phone

+98 86 3222 2003

Fax

+98 86 3222 2003

Email

alikamaliir@yahoo.com

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