

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

comparing the effect of aspirin and the combination of aspirin with Osvox after surgery, on surgery outcomes in patients are candidates for Coronary artery bypass grafting

Protocol summary

Study aim

comparing the effect of aspirin and the combination of aspirin with Osvox after surgery, on surgery outcomes in patients are candidates for Coronary artery bypass grafting

Design

The study of the two-course clinical trial of 130 patients was randomly divided into 2 groups. The groups are parallel. The trial phase is 3.

Settings and conduct

candidates for Coronary artery bypass grafting in Amirmomenin hospital in Arak are divided into 2 groups by simple randomization with envelopes. The study is double-blind in which outcome evaluator and data analyst and participant are kept blind

Participants/Inclusion and exclusion criteria

Inclusion criteria: both of gender, candidates for Coronary artery bypass grafting Exclusion criteria: dissatisfaction, death

Intervention groups

First group: receive aspirin 80mg (Jalinos company) daily. Second group: is given aspirin 80mg (Jalinos company) daily and Osvox (Osveh company) daily at a dose of 75 mg, both for three months at 12 noon.

Main outcome variables

Incidence of myocardial infarction, bleeding, platelet count, cell pack count, FFP received

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020258N157**

Registration date: **2021-04-25, 1400/02/05**

Registration timing: **prospective**

Last update: **2021-04-25, 1400/02/05**

Update count: **0**

Registration date

2021-04-25, 1400/02/05

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-22, 1400/03/01

Expected recruitment end date

2022-05-22, 1401/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparing the effect of aspirin and the combination of aspirin with Osvox after surgery, on surgery outcomes in patients are candidates for Coronary artery bypass grafting

Public title

comparing the effect of aspirin and the combination of

aspirin with Osrix after surgery, on surgery outcomes in patients are candidates for Coronary artery bypass grafting

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Both of gender Candidates for Coronary artery bypass grafting

Exclusion criteria:

dissatisfaction

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **130**

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

Outcome assessor and data analyzer and participant are blind (double blind). Outcome assessor and data 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

2020-12-13, 1399/09/23

Ethics committee reference number

IR.ARAKMU.REC.1399.277

Health conditions studied

1

Description of health condition studied

Coronary artery bypass grafting

ICD-10 code

T82.2

ICD-10 code description

Mechanical complication of coronary artery bypass and valve grafts

Primary outcomes

1

Description

Incidence of myocardial infarction

Timepoint

6 months after surgery

Method of measurement

Physical examination

2

Description

Received platelets

Timepoint

72 hours after surgery

Method of measurement

Observation

3

Description

Bleeding

Timepoint

To 72 hours after surgery

Method of measurement

Millilitre

4

Description

Packcell amount received

Timepoint

To 72 hours after surgery

Method of measurement

Observation

5

Description

FFP received

Timepoint

To 72 hours after surgery

Method of measurement

Observation

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: receive aspirin 80mg (Jalinos company) daily

Category

Treatment - Drugs

2

Description

Intervention group: is given aspirin 80 mg (Jalinos company) daily and Osvox (Osveh company) daily at a dose of 75 mg, both for three months at 12 noon.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amiralmomenin hospital

Full name of responsible person

Dr Alireza Kamali

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Sponsors / Funding sources

1

Sponsor

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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 scientific inquiries**Contact****Name of organization / entity**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

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

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

Undecided - It is not yet known if there will be 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