Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effect of local epinephrine and norepinephrine on postoperative outcomes in candidate patients for coronary artery bypass graft:RCT

Protocol summary

Study aim
Comparison of the effect of local epinephrine and norepinephrine on local surgical outcomes

Design
It is a randomized clinical trial study in which 123 patients were randomly divided into three completely equal groups using software randomized blocking and examined as double-blind. The study groups are included: the control group, the first intervention group, and the second intervention group.

Settings and conduct
In this randomized clinical trial i patients with Arterial Bypass Graft coronary artery disease referred to Amir Al-Momenin Hospital in Arak enter the study after obtaining written consent and having entry criteria. 123 patients will be examined and will be randomly assigned in groups and in the form of double-blind. In this study, the surgeon, the patient and the clinical assessors are blind.

Participants/Inclusion and exclusion criteria
1- Non-emergency CABG candidate patients who have agreed to participate in the project 2- ASA patients in 3 and 4 classes 3- All patients with less than 6 hours of surgical duration 4 - Patients who are in the age range of 45 to 80 years

Intervention groups
In the epinephrine group, one epinephrine vial is ingested in 50 cc of normal saline and poured into the pericardial area. In the norepinephrine group, half a vial of epinephrine is ingested and washed within 50 cc of normal saline, and in the third group, 50 cc of normal saline is poured alone into the pericardial area and washed.

Main outcome variables
Bleeding rate; patient hemoglobin level; length of stay in ICU

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200603047645N1**
Registration date: **2020-06-21, 1399/04/01**
Registration timing: **retrospective**

Last update: **2020-06-21, 1399/04/01**
Update count: **0**

Registration date
2020-06-21, 1399/04/01

Registrant information

Name
Marjan Abdoli

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 2280 3104

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-12-11, 1398/09/20

Expected recruitment end date
2020-06-21, 1399/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of local epinephrine and norepinephrine on postoperative outcomes in candidate patients for coronary artery bypass graft:RCT

Public title
Effect of epinephrine on coroner bypass graft
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Non-emergency CABG candidate patients who have agreed to participate in the project All patients with ASA class 3 and 4 All patients whose surgery duration is less than 6 hours
Exclusion criteria:
Patients who underwent emergency CABG surgery Patients who do not have a consent to participate in the project Patients who, in addition to CABG, are candidates for valve replacement surgery Patients who had more than 6 hours of surgery
Age
From **45 years** old to **80 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **123**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, 123 patients were divided into three completely equal blocks using epinephrine, norepinephrine, and placebo at three times during sampling using software randomized blocking.
Blinding (investigator's opinion)
Double blinded
Blinding description
After surgery, patients are divided into A B C groups. The first group is the placebo group, where normal saline is poured on the heart. Be. In all three groups, the drug is prepared in the same size and with the same color and shape for patients, which is acceptable in terms of blindness and blinding surgery. Also, the person in charge of the project, who is responsible for filling out the checklist, is not aware of the type of groups based on the injection drug, and only recognizes the groups based on A, B, and C, and fills the checklists accordingly.
Placebo
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
Payambar-e-Azam Complex, Sardasht
City
Arak
Province
Markazi
Postal code
3819693345
Approval date
2019-01-13, 1397/10/23
Ethics committee reference number
IR.ARAKMU.REC.1397.288

Health conditions studied

1

Description of health condition studied
Coronary artery bypass graft
ICD-10 code
I25.7
ICD-10 code description
Atherosclerosis of coronary artery bypass graft(s) and coronary artery of transplanted heart with angina pectoris

Primary outcomes

1

Description
Bleeding 24 hours after surgery
Timepoint
24 hours after surgery
Method of measurement
Suction the amount of bleeding in the calibrated container

Secondary outcomes

1

Description
Lenght of stay at the ICU
Timepoint
When leaving the ICU
Method of measurement
Calculation from the date of surgery

2

Description
Patient's hemoglobin level after surgery
Timepoint
After surgery
Method of measurement
Complete Blood Count

Intervention groups

1

Description
Control group: After the operation, 50 cc of normal saline is poured into the pericardium area alone and washed.
Category
Placebo

2

Description
First Intervention group: After the operation: An epinephrine vial (1mg) is immersed in 50 cc of normal saline and poured into the pericardium.
Category
Treatment - Drugs

3

Description
Second intervention group: After surgery, half of the norepinephrine (2 mg) vial is immersed in 50 cc of normal saline and washed.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Amir-al-momenin hospital
Full name of responsible person
Marjan Abdoli
Street address
Basij Sq., Sardasht Town
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3848176941
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Alireza Kamali
Street address
Payambar-e-azam Complex, Basij Sq., Sardasht Town
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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
Marjan Abdoli
Position
Student
Latest degree
A Level or less
Other areas of specialty/work
General Practitioner
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Person responsible for updating data

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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