# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

02 Jul 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)

**Phone**

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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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## Sponsors / Funding sources

**1**

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

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## Person responsible for updating data

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**Latest degree**
A Level or less

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General Practitioner

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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