

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparison of simultaneous antegrade.venous graft cardioplegia infusion to conventional method in coronary artery bypass grafting

Protocol summary

Summary

Objective: To determine the ideal method for cardiac arresting during CABG in order to decrease the incidence of low cardiac output syndrome following surgery.

Design: Double blind randomized clinical trial, parallel recruitment. Double blind means that neither data collectors and analyzers nor the patients are aware of the allocation criteria. Main inclusion criteria: Coronary artery disease patients scheduled for first-time elective isolated on-pump CABG. Main exclusion criteria: Unstable patients undergoing urgent CABG. Sample size: At least 89 individuals in either intervention or control group.

Intervention: Continuous crystalloid cardioplegia infusion through saphenous vein grafts, after each distal anastomosis completed, in addition to conventional intermittent antegrade method via aortic root consisting of blood cardioplegia. Duration of study: Approximately one year. Primary end-points: The need for intra-aortic balloon pump and inotrope during and after weaning. Main secondary end-points: The rate of postoperative arrhythmia, the peak level of serum biomarkers of myocardial injury, i.e. CK, CK-MB, and cardiac troponin I (cTnI), at 12 hours following surgery, arterial level of base excess (BE) in the ICU, ventilation time, the length of ICU and hospital stay and finally hospital mortality.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017102625488N2**
Registration date: **2017-11-04, 1396/08/13**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-11-04, 1396/08/13

Registrant information

Name

Mehrzaad Sharifi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 86 3313 6055

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Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences

Expected recruitment start date

2017-11-01, 1396/08/10

Expected recruitment end date

2018-11-01, 1397/08/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of simultaneous antegrade.venous graft cardioplegia infusion to conventional method in coronary artery bypass grafting

Public title

Effect of method of cardiac arresting on outcomes following bypass surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Coronary artery disease patients scheduled for first-time elective isolated on-pump CABG
Exclusion criteria: 1. Redo CABG 2. Urgent CABG 3. Off-

pump CABG 4. Combined operations including CABG in addition to valve repair or replacement 5. Unexpected intra-operative complications e.g. aortic rupture during cannulation

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 178

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Simple randomization technique using SAS software version 9.4 will be applied for randomized allocation.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Arak University of Medical Sciences

Street address

Arak University of Medical Sciences, Shahid Shiroodi st., Alamolhoda st.

City

Arak

Postal code

Approval date

2017-10-22, 1396/07/30

Ethics committee reference number

IR.ARAKMU.REC.1396.144

Health conditions studied

1

Description of health condition studied

Coronary artery disease

ICD-10 code

I25.1

ICD-10 code description

Atherosclerotic heart disease

2

Description of health condition studied

Coronary artery bypass graft

ICD-10 code

T82.2

ICD-10 code description

Mechanical complication of coronary artery bypass and valve grafts

Primary outcomes

1

Description

The need for balloon pump

Timepoint

During and after weaning

Method of measurement

Number (percentage)

2

Description

The need for inotrope

Timepoint

During and after weaning

Method of measurement

Number (percentage)

Secondary outcomes

1

Description

Other complications including neurologic, renal, and pulmonary complications

Timepoint

Within one month after surgery

Method of measurement

Number (percentage)

2

Description

The amount of bleeding

Timepoint

Within 24 hours following surgery

Method of measurement

mL

3

Description

Serum level of potassium

Timepoint

Immediately upon arrival to ICU

Method of measurement

mEq/L

4

Description

The rate of perioperative myocardial infarction

Timepoint

During hospitalization

Method of measurement

Number (percentage)

5

Description

Hospital mortality

Timepoint

During hospitalization

Method of measurement

Number (percentage)

6

Description

The rate of postoperative arrhythmia

Timepoint

During ICU stay

Method of measurement

Number (percentage)

7

Description

Peak serum level of CK, CK-MB, and cTnI

Timepoint

At 12 hours following operation in the ICU

Method of measurement

mcg/L

8

Description

The rate of superficial or deep wound infection

Timepoint

During hospitalization

Method of measurement

Number (percentage)

9

Description

The rate of re-exploration due to hemorrhage or tamponade

Timepoint

Within 24 hours following surgery in the ICU

Method of measurement

Number (percentage)

10

Description

Ventilation time

Timepoint

Within 24 hours following surgery in the ICU

Method of measurement

Hours

11

Description

Arterial level of base excess (BE)

Timepoint

Within one hour after arrival to ICU

Method of measurement

mmol/L

12

Description

Duration of ICU stay

Timepoint

following surgery

Method of measurement

Days

13

Description

Duration of hospital stay

Timepoint

following surgery

Method of measurement

Days

Intervention groups

1

Description

Intervention group: Mostly crystalloid cardioplegia (2% blood to prevent obscuring of the operative field), is infused continuously through vein grafts by a separate infusion set, once each distal anastomosis is completed at a rate of 10 to 20 mL per minute. This infusion is continued until half of the last distal anastomosis performed. The traditional method of intermittent cold blood (4 degrees Celsius) cardioplegia instillation, repeated every 20 minutes is implemented as well.

Category

Treatment - Surgery

2

Description

Control group: Antegrade cold blood cardioplegia (at a ratio of 4 to 1) is infused via aortic root by means of a cannula inserted by the surgeon at the middle part of ascending aorta. This injection conducting by the perfusionist, usually lasts about 3 minutes and should be repeated every 20 minutes (intermittent fashion).

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Amiralmomenin Hospital

Full name of responsible person

Dr. Mehrzad Sharifi

Street address

Sardasht square. Arak. Iran

City

Arak

m.sharifi@arakmu.ac.ir

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Mehrzad Sharifi

Position

Assistant professor in cardiovascular surgery

Other areas of specialty/work**Street address**

Cardiac surgery department, Amiralmomenin hospital, Sardasht square

City

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Postal code**Phone**

+98 86 3417 3602

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m.sharifi@arakmu.ac.ir

Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice chancellor for research and technology, Arak University of Medical Sciences

Full name of responsible person

Mohammad Arjmand zadegan

Street address

Vice chancellor for research and technology, Arak University of Medical Sciences, Basij square.

City

Arak

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research and technology, Arak University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Mehrzad Sharifi

Position

Assistant professor in cardiovascular surgery

Other areas of specialty/work**Street address**

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Fax**Email****Person responsible for updating data****Contact****Name of organization / entity**

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code
empty

Data Dictionary
empty