

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of Short- and Mid-term Outcomes of Off-pump and On-pump Coronary Artery Bypass Grafting (CABG) surgery in Patients With 3-vessel Coronary Artery Disease: A Randomized Clinical Trial

Protocol summary

Study aim

Comparison of short-term and medium-term complications of on-pump vs. off-pump coronary artery bypass grafting

Design

the randomized trial, phase 4, randomized by the method of blocks of 4 in two equal parallel groups (off-pump and on-pump) of 274 patients.

Settings and conduct

All surgeries were performed at the Tehran Heart Center by a high-experienced surgeon in both methods with and without the use of a cardiopulmonary pump device. Due to the nature of the intervention (type of surgery), blinding of the intervention was done for the patients, post-operative follow-up doctors, and data analysts.

Participants/Inclusion and exclusion criteria

inclusion criteria: patients with three vessels coronary disease requiring coronary artery bypass grafting surgery. exclusion criteria: Patients with Single-vessel CAD and/or other concomitant cardiac surgery such as valve replacement, aorta reconstruction, or other additional cardiovascular disease necessitating concomitant surgery were excluded.

Intervention groups

The first group: patients who undergo coronary artery bypass surgery using the on-pump method. The second group: patients who undergo coronary artery bypass surgery by the off-pump method.

Main outcome variables

major adverse cardiovascular events (MACE) including all-cause mortality, acute coronary syndrome, stroke or transient ischemic attack, and the need for repeat revascularization (percutaneous coronary intervention or redo-CABG).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190120042428N1**

Registration date: **2022-09-16, 1401/06/25**

Registration timing: **retrospective**

Last update: **2022-09-16, 1401/06/25**

Update count: **0**

Registration date

2022-09-16, 1401/06/25

Registrant information

Name

seyed khalil forouzannia

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 8802 9707

Email address

drforouzan_nia@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-20, 1399/03/31

Expected recruitment end date

2020-12-21, 1399/10/01

Actual recruitment start date

2020-06-20, 1399/03/31

Actual recruitment end date

2020-12-20, 1399/09/30

Trial completion date

empty

Scientific title

Comparison of Short- and Mid-term Outcomes of Off-pump and On-pump Coronary Artery Bypass Grafting (CABG) surgery in Patients With 3-vessel Coronary Artery Disease: A Randomized Clinical Trial

Public title

Evaluation of short-term and mid-term results of using a cardiopulmonary pump in coronary artery bypass graft surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

patients with 3 vessels coronary artery disease
Candidates for coronary artery bypass graft surgery

Exclusion criteria:

require emergency operation combined valve surgery
history of cardiac surgeries patients with cardiogenic shock patients with preoperative Intra-aortic balloon pump patients with single or two vessel disease patients with contraindication to off-pump CABG history of renal failure

Age

From **18 years** old

Gender

Both

Phase

4

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **272**

Actual sample size reached: **263**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done by the method of "limited randomization" and using the method of blocks of equal size (each block of four patients). By convention, we assign two letters A and B to each type of surgery (off-pump and on-pump). In each block, we will have different permutations of A and B, but an equal number of each intervention (2 to A and 2 to B). In this way, we will have six blocks. Then the sequence of these blocks will be made randomly by the random sequence generation software "Random Allocation Software", which according to the sample size of 272, we will have 68 blocks. Then, in order to hide the random allocation, the "central randomization" method will be used. In this method, sequence information will be provided to someone outside of the study process in the research center, and researchers will be informed of the type of intervention assigned to that patient by phone call based on the order of patients entering the study. This process will continue until the last patient.

Blinding (investigator's opinion)

Double blinded

Blinding description

According to the contract, one of the letters A and B is assigned to each type of surgery (Off-pump and On-pump) before the start of the study. Due to the nature of the intervention (type of surgery), which cannot be blinded for the surgeon and the main staff of the surgical team, blinding of the intervention is done for the patients, doctors, and those responsible for collecting the data of the outcome of the post-surgery study and the data analyst, and these people They will not know about the type of intervention assigned to groups A and B, and in the information available to these people, the type of intervention is indicated by the letters mentioned.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tehran Heart Center

Street address

North Kargar-Ave

City

Tehran

Province

Tehran

Postal code

1411713138

Approval date

2020-06-20, 1399/03/31

Ethics committee reference number

IR.TUMS.THC.REC.1399.005

Health conditions studied

1

Description of health condition studied

coronary artery disease

ICD-10 code

I25.1

ICD-10 code description

Atherosclerotic heart disease of native coronary artery

Primary outcomes

1

Description

major adverse cardiovascular events (MACE)

Timepoint

1, 3, 6, 12 months after surgery and then every 6

months until the end of the study

Method of measurement

The occurrence and type of major adverse cardiovascular events will be recorded during routine visits after surgery (at 1, 3, 6, and 12 month intervals) and at other intervals by telephone follow-up.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: patients who underwent coronary artery bypass surgery without the use of a cardiopulmonary pump device. In these patients, the anastomosis of the graft vessels on the coronary vessels will be performed on the beating heart, and the surgical area will be kept stable by standard stabilizers. Other surgical procedures will be the same as the conventional On-pump method.

Category

Treatment - Surgery

2

Description

Control group: patients who undergo surgery using a cardiopulmonary pump device. In these cases, using cardioplegic drugs and cannulating the aorta, and transferring blood pumping to the cardiopulmonary pump device, graft anastomosis will be performed on the coronary arteries in the condition of a heart without beating. Other surgical procedures will be similar to the Off-pump method.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran Heart Center

Full name of responsible person

Seyed Khalil Forouzannia

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Research Council of Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Seyed Khalil Forouzannia

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

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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

No - There is not 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

All clinical information of patients without personal information after patient de-identification

When the data will become available and for how long

Six months after the publication of the results

To whom data/document is available

All biological science researchers

Under which criteria data/document could be used

For inclusion in review studies or referring to result of current study in publications

From where data/document is obtainable

The data will be accessible by sending an official request to mmd.forouzan@gmail.com

What processes are involved for a request to access data/document

Requests will be accessible to the requester by sending the data file via email after being reviewed by the Tehran Heart Center Research Council

Comments