Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 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
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seyed khalil forouzannia
Name of organization / entity
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Iran (Islamic Republic of)
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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