

# 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

##### Name

seyed khalil forouzannia

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+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

##### **Street address**

North Kargar-Ave , Tehran-Iran

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

88029731

##### **Phone**

+98 21 8802 9600

##### **Email**

mmd.forouzan@gmail.com

#### **Sponsors / Funding sources**

##### **1**

#### **Sponsor**

##### **Name of organization / entity**

Tehran University of Medical Sciences

##### **Full name of responsible person**

Akbar Fotouhi

##### **Street address**

North Kargar-Ave , Tehran-Iran

##### **City**

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##### **Province**

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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**

Cardiology

##### **Street address**

North Kargar-Ave , Tehran-Iran

##### **City**

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## Person responsible for scientific inquiries

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**Position**

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## Person responsible for updating data

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**Position**

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**Latest degree**

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mmd.forouzan@gmail.com

## 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**