

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Comparison of single versus sequential aortic side biting clamp for restoration of venoarterial anastomosis in coronary artery bypass surgery (CABG) patients

#### Protocol summary

##### Study aim

Comparison of single versus sequential aortic side biting clamp for restoration of venoarterial anastomosis in CABG patients.

##### Design

In the present clinical trial, which will be carried out in a parallel way, a total of 58 patients who will be undergoing coronary artery bypass surgery will be enrolled. Eligible patients are divided into two equal groups A and B.

##### Settings and conduct

Candidates for Coronary artery bypass graft surgery who visit Namazee Shiraz Hospital during the study will be included in the study if they are eligible and will be non-randomly assigned to the intervention and control groups.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients between 18 and 40 years old, Candidate for coronary artery bypass surgery with a diagnosis of coronary artery occlusion and Patient's informed consent. Exclusion criteria: Positive history of valvular heart diseases and myocardial infarction, Patients who are at risk of cerebral embolism during ascending aorta clamping.

##### Intervention groups

Control group: In order to perform coronary artery bypass surgery, two surgeons who were similar in terms of surgery time and technique were selected. For the proximal anastomoses of the saphenous vein to the ascending aorta, simple partial clamp technique was used in the control group. In this method, a large lateral vascular clamp is placed on the ascending aorta And all the proximal anastomoses of the vein to the aorta are done by placing this same clamp. Intervention group: In the Sequential partial aortic clamp method, a relatively small or medium vascular clamp was used, which closed a small amount of the aorta wall in each stage. At each

stage, only one hole in the aorta wall were performed and after the end of each anastomosis, the clamp was opened and placed in another part of the aorta.

##### Main outcome variables

Cardiac arrhythmia

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20240121060750N1**

Registration date: **2024-03-03, 1402/12/13**

Registration timing: **retrospective**

Last update: **2024-03-03, 1402/12/13**

Update count: **0**

##### Registration date

2024-03-03, 1402/12/13

##### Registrant information

##### Name

Reza Khajeh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3739 8813

##### Email address

khaje\_r@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2014-06-22, 1393/04/01

##### Expected recruitment end date

2015-06-22, 1394/04/01

**Actual recruitment start date**

2014-06-22, 1393/04/01

**Actual recruitment end date**

2015-06-22, 1394/04/01

**Trial completion date**

2015-07-21, 1394/04/30

**Scientific title**

Comparison of single versus sequential aortic side biting clamp for restoration of venoaortic anastomosis in coronary artery bypass surgery (CABG) patients

**Public title**

Comparison of two methods of coronary artery bypass surgery.

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients between 18 and 40 years old Candidate for coronary artery bypass surgery with a diagnosis of coronary artery occlusion. Patient's informed consent

**Exclusion criteria:**

Positive history of valvular heart diseases Positive history of recent myocardial infarction Patients who were at risk of cerebral embolism during ascending aorta clamping

**Age**

From **18 years** old to **80 years** old

**Gender**

Both

**Phase**

1-2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **60**

Actual sample size reached: **58**

**Randomization (investigator's opinion)**

Not randomized

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Shiraz Medical School

**Street address**

3rd Floor, Building number 3 of Shiraz Medical School,

Zand Blvd.

**City**

Shiraz

**Province**

Fars

**Postal code**

7134844119

**Approval date**

2014-06-22, 1393/04/01

**Ethics committee reference number**

IR.SUMS.REC.1393.6509

**Health conditions studied****1****Description of health condition studied**

Coronary Artery Bypass Grafting

**ICD-10 code**

I25.810

**ICD-10 code description**

Atherosclerosis of coronary artery bypass graft(s) without angina pectoris

**Primary outcomes****1****Description**

Troponin

**Timepoint**

before operation (base),just after operation,24 hours after operation.

**Method of measurement**

ج

**2****Description**

creatine phosphokinase

**Timepoint**

before operation (base),just after operation,24 hours after operation.

**Method of measurement**

elisa

**3****Description**

Cardiac arrhythmia

**Timepoint**

During the operation, after the operation.

**Method of measurement**

Cardiac monitoring

**Secondary outcomes**

empty

**Intervention groups**

## 1

### Description

Control group: In order to perform coronary artery bypass surgery, two surgeons who were similar in terms of surgery time and technique were selected. All surgeries were performed by open heart surgery, under cardiopulmonary pump and cardiac arrest, by injecting cold cardioplegic fluid in the ascending aorta. For the proximal anastomoses of the saphenous vein to the ascending aorta, simple partial clamp technique was used in the control group. In the simple partial clamp method, a large lateral vascular clamp is placed on the ascending aorta, and holes are created in the aorta wall with the number of vein clamps to the aorta by a punch device. All the proximal anastomoses of the vein to the aorta are done by placing this same clamp, and after the end of the last anastomosis, the vascular clamp is opened. While performing all the proximal anastomoses, the previously grafted areas are not supplied with blood

### Category

Treatment - Surgery

## 2

### Description

Intervention group: In the Sequential partial aortic clamp method, a relatively small or medium vascular clamp is used, which closes a small amount of the aorta wall in each stage. At each stage, only one hole in the aorta wall and only one anastomosis between the vein and the aorta were performed. After the end of each anastomosis, the clamp is opened and placed in another part of the aorta, and the next anastomosis is performed in the same way. Therefore, in this method, from the second anastomoses onwards, the previously grafted parts of the myocardium are supplied with blood.

### Category

Treatment - Surgery

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Nemazee Hospital

**Full name of responsible person**

Reza Khajeh

**Street address**

Nemazee Hospital, Namazi Square, Zand Street.

**City**

Shiraz

**Province**

Fars

**Postal code**

7193613311

**Phone**

+98 71 3647 4332

**Email**

Nemazee\_inf@sums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Mohammad hashem Hashempour

**Street address**

7th floor, central building of Shiraz University of Medical Sciences, Vice Chancellor of research, Zand street.

**City**

Shiraz

**Province**

Fars

**Postal code**

7134844119

**Phone**

+98 71 3235 7282

**Email**

hashempur@gmail.com

**Web page address**

<https://rde.sums.ac.ir>

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

Yes

**Title of funding source**

Shiraz 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**

Shiraz University of Medical Sciences

**Full name of responsible person**

Reza Khajeh

**Position**

Non-academic heart surgeon

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Cardiology

**Street address**

Al-Zahra(S) Hospital, Astana Three Roads, Siboye Blvd.

**City**

Shiraz

**Province**  
Fars  
**Postal code**  
54937-71649  
**Phone**  
+98 71 3839 8113  
**Email**  
drrkhajeh@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Shiraz University of Medical Sciences  
**Full name of responsible person**  
Khalil Zarrabi  
**Position**  
Associate Professor of Cardiovascular Surgery  
**Latest degree**  
Subspecialist  
**Other areas of specialty/work**  
Cardiology  
**Street address**  
Al-Zahra(S) Hospital, Astana Three Roads, Siboye Blvd.  
**City**  
Shiraz  
**Province**  
Fars  
**Postal code**  
54937-71649  
**Phone**  
+98 71 3839 8113  
**Email**  
zarrabisx@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**

Shiraz University of Medical Sciences  
**Full name of responsible person**  
Hamide Saeedizade  
**Position**  
Research Assisstant  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Medical Informatics  
**Street address**  
Faghihi Hospital, Anesthesiology Department, Zand Street  
**City**  
Shiraz  
**Province**  
Fars  
**Postal code**  
7134844119  
**Phone**  
+98 71 3628 1460  
**Email**  
saeedi.hamide@gmail.com

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

### Justification/reason for indecision/not sharing IPD

It is against our policy.

### Study Protocol

No - There is not a plan to make this available

### Statistical Analysis Plan

No - There is not a plan to make this available

### Informed Consent Form

No - There is not a plan to make this available

### Clinical Study Report

No - There is not a plan to make this available

### Analytic Code

No - There is not a plan to make this available

### Data Dictionary

No - There is not a plan to make this available