

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jun 2026

### Effect of Propofol Cardioplegia Solution on Myocardial Injury Bio marker in Coronary Artery Bypass Grafting Surgery

#### Protocol summary

2019-01-06, 1397/10/16

#### Study aim

Effect of Propofol Cardioplegia Solution on Myocardial Injury Bio marker in Coronary Artery Bypass Grafting Surgery

#### Design

Double Blinded Randomized Clinical Trial; sample size: 120 case; clinical phase: 2-3

#### Settings and conduct

Namazi and alzahra heart Hospital

#### Participants/Inclusion and exclusion criteria

Inclusion criteria: patients who are undergoing elective CABG. Exclusion criteria: Redo operation; emergency CABG for threatened myocardial infarction; Primary troponin level above 3 µg /L; severe renal failure; severe liver failure; congestive heart failure grade IV; Ejection fraction lower than 30%; Food Allergy ( eggs, soy, peanuts).

#### Intervention groups

Intervention group: Patients in the intervention group received 1200 µg / min propofol by syringe pump as a cardioplegic solution. Control group: Patients in the control group received cardioplegic solution without adding propofol.

#### Main outcome variables

serum level of troponin I; serum level of CPKMB

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180922041084N2**

Registration date: **2019-01-06, 1397/10/16**

Registration timing: **prospective**

Last update: **2019-01-24, 1397/11/04**

Update count: **1**

##### Registration date

#### Registrant information

##### Name

Maryam Tabibzadeh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3628 1460

##### Email address

dpt2370349433@sums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

#### Expected recruitment start date

2019-02-26, 1397/12/07

#### Expected recruitment end date

2019-05-28, 1398/03/07

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Effect of Propofol Cardioplegia Solution on Myocardial Injury Bio marker in Coronary Artery Bypass Grafting Surgery

#### Public title

Effect of Propofol Cardioplegia Solution on Myocardial Injury Bio marker

#### Purpose

Prevention

#### Inclusion/Exclusion criteria

##### Inclusion criteria:

Patient who are candidate for elective Coronary Artery Bypass surgery

**Exclusion criteria:**

Redo surgery Primary troponin level is above 3 µg / L  
sever Renal failure sever Liver failure congestive Heart  
Failure grade IV Ejection fraction lower than 30% Allergy  
to eggs, soy, peanuts

**Age**

From **30 years** old to **75 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor

**Sample size**

Target sample size: **120**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Patients were randomized according to the charts which  
was derived from www.randomization.com site.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

A nurse who is unaware of the study groups will provide  
the cardioplegic solution and will deliver cardioplegic  
solution to the nurse responsible for anesthesia for  
injection. The investigators in the operation room and in  
the ward are unaware of the study groups.

**Placebo**

Not used

**Assignment**

Parallel

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

empty

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

Ethics Committee of Shiraz University of Medical  
Sciences

**Street address**

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

**City**

Shiraz

**Province**

Fars

**Postal code**

7134844119

**Approval date**

2018-08-23, 1397/06/01

**Ethics committee reference number**

IR.SUMS.REC.1397.415

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

atherosclerosis

**ICD-10 code**

I25.1

**ICD-10 code description**

Atherosclerotic heart disease

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

serum level of troponin I

**Timepoint**

1st sample just after induction ,2nd sample just after  
chest closure , 3rd sample 6 hours after arrival to ICU  
and last sample 24 hours after arrival to the ICU

**Method of measurement**

Lab test

**2****Description**

serum level of CPKMB

**Timepoint**

1st sample just after induction ,2nd sample just after  
chest closure , 3rd sample 6 hours after arrival to ICU  
and last sample 24 hours after arrival to the ICU

**Method of measurement**

Lab test

**Secondary outcomes****1****Description**

Arhythmia

**Timepoint**

During operation and after that

**Method of measurement**

Monitoring

**Intervention groups****1****Description**

Intervention group:Patients in the intervention group  
received 1200 µg / min propofol by syringe pump as a  
cardioplegic solution.

**Category**

Prevention

## 2

### Description

Control group: Patients in the control group received cardioplegic solution without adding propofol .

### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Nemazi Hospital and Alzahra Heart Hospital

##### Full name of responsible person

Gholam ali Heidari kochi

##### Street address

Hazrat vali asr Hospital

##### City

Fasa

##### Province

Fars

##### Postal code

7461477587

##### Phone

+98 71 5336 2449

##### Email

perfusion.heidari@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Full name of responsible person

Dr Younes Ghasemi

##### Street address

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

##### City

Shiraz

##### Province

Fars

##### Postal code

7134844119

##### Phone

+98 71 3647 4270

##### Email

drtabib.maryam@yahoo.com

##### 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

Gholam Ali Heidari kochi

##### Position

master student of perfusional technology

##### Latest degree

Bachelor

##### Other areas of specialty/work

Nursery

##### Street address

Mohammad Rasoul Allah Research Tower, Khalili Street

##### City

Shiraz

##### Province

Fars

##### Postal code

7134844119

##### Phone

+98 71 3647 4270

##### Email

drtabib.maryam@yahoo.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Full name of responsible person

Reza Jouybar

##### Position

Fellowship of Cardioanesthesiology

##### Latest degree

Specialist

##### Other areas of specialty/work

Anesthesiology

##### Street address

Anesthesiology Department, Faghihi Hospital, Zand Street

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##### Province

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##### Postal code

7134844119

##### Phone

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**Email**

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

Shiraz University of Medical Sciences

**Full name of responsible person**

Maryam Tabibzadeh

**Position**

General physician

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Anesthesiology

**Street address**

5th floor, Mohammad Rasoul Allah Research Tower,  
Khalili Street

**City**

Shiraz

**Province**

Fars

**Postal code**

7134844119

**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available