

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 May 2026

### Comparison of the two methods: using custodiol versus combined custodiol and modified delnido on myocardial protection in Cardiac surgeries.

#### Protocol summary

##### Study aim

comparing tow methodes: custodiol and modified combination with custodiol and its effect on myocardial protection

##### Design

single blinded randomized clinical trial with parallel group

##### Settings and conduct

40 patients undergoing CABG were divided into to group; 1: Patients in the intervention group one will receive 15 cc per /kg of cold modified delnido cardioplegia solution with 1000 cc custodiol during 2-4 min with anti-grade method. Patients in the intervention group two will receive 20 cc per/ kg cold custodiol solution during 6-8 min with anti-grade method.

##### Participants/Inclusion and exclusion criteria

criteria for entering to study: patients under coronary artery bypass graft with ejection fraction below 30 %, redo coronary artery bypass graft surgeries, coronary artery bypass graft surgery with valve surgery criteria for exiting from study: emergent surgery, recently myocardial infarction, renal failur

##### Intervention groups

group; 1: 15cc per kg of cold modified delnido cardioplegia solution with 1000 cc custodiol will injected at period of 2-4 min with antigrade method. 2; 20 cc per kg cold custodiol solution at period of 6-8 min will injected antigradely

##### Main outcome variables

primary outcome: serum level of CK-MB and Troponin at the induction time, 2 hours after operation and 48 hours after operation . Secondary outcome : dysrhythmia during and after operation and defibrillation requirement during operation and mortality rate.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190411043239N1**

Registration date: **2019-05-24, 1398/03/03**

Registration timing: **prospective**

Last update: **2019-05-24, 1398/03/03**

Update count: **0**

##### Registration date

2019-05-24, 1398/03/03

##### Registrant information

##### Name

Neda Reihanifard

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3620 3853

##### Email address

nedaaa.reihanifard@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-06-20, 1398/03/30

##### Expected recruitment end date

2019-08-22, 1398/05/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Comparison of the two methods: using custodiol versus combined custodiol and modified delnido on myocardial protection in Cardiac surgeries.

## Public title

Comparison of the two methods: using custodiol versus combined custodiol and modified delnido on myocardial protection in Cardiac surgeries.

## Purpose

Prevention

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patients under coronary artery bypass graft with ejection fraction below 30 % Redo coronary artery bypass graft surgeries Coronary artery bypass graft surgery with valve surgery

### Exclusion criteria:

Emergency surgery Recently myocardial infarction Renal failure

## Age

No age limit

## Gender

Both

## Phase

2-3

## Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

## Sample size

Target sample size: 40

## Randomization (investigator's opinion)

Randomized

## Randomization description

According to the randomized chart which was derived from [www.randomization.org](http://www.randomization.org)

## Blinding (investigator's opinion)

Single blinded

## Blinding description

The patient and anesthesia nurse who takes venous blood samples in the operating room and also the nurse who takes the second and third samples in the ICU and the laboratory instructor does not know the type of patient group. The only person who is aware of the study group is perfusionist who is injected a cardioplegia solution.

## 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

7185656948

#### Approval date

2019-02-20, 1397/12/01

#### Ethics committee reference number

IR.SUMS.REC.1398.124

## Health conditions studied

## 1

### Description of health condition studied

arteriosclerosis

### ICD-10 code

I25.10

### ICD-10 code description

Atherosclerotic heart disease of native coronary artery without angina pectoris

## Primary outcomes

## 1

### Description

Serum level of CK\_MB

### Timepoint

induction time, 2 h after operation and 48 h after operation

### Method of measurement

venous blood sample

## 2

### Description

Serum level of Troponin

### Timepoint

induction time, 2 h after operation and 48 h after operation

### Method of measurement

venous blood sample

## Secondary outcomes

## 1

### Description

cardiac dysrhythmia

### Timepoint

induction time, 2h after operation and 48 h after operation

**Method of measurement**  
monitoring

## Intervention groups

### 1

#### Description

Intervention group 1: Patients in the intervention group one will receive 15 cc per /kg of cold modified delnido cardioplegia solution with 1000 cc custodiol during 2-4 min with anti-grade method

#### Category

Prevention

### 2

#### Description

intervention group2: Patients in the intervention group two will receive 20 cc per/ kg cold custodiol solution during 6-8 min with anti-grade method.

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Ordibehesht hospital

##### Full name of responsible person

Kazem Chabok

##### Street address

Chamran boulevard, Ordibehesht hospital

##### City

Shiraz

##### Province

Fars

##### Postal code

7189656948

##### Phone

+98 71 3628 4821

##### Email

info@ordibeheshthospital.ir

### 2

#### Recruitment center

##### Name of recruitment center

Shiraz central hospital

##### Full name of responsible person

Mohamad Reza Khoshnood

##### Street address

Chamran boulevard, Shiraz Central hospital

##### City

Shiraz

##### Province

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##### Postal code

7189656948

##### Phone

+98 71 3628 4411

##### Email

Astalavish@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Full name of responsible person

Younes Ghasemi

##### Street address

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

##### City

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##### Province

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##### Postal code

7189678548

##### Phone

+98 71 3230 5410

##### Email

vcrdep@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

Neda reihanifard

##### Position

Cardiac perfusionist /student

##### Latest degree

Bachelor

##### Other areas of specialty/work

Cardiology

##### Street address

Anesthesiology Department, Faghihi Hospital, Zand Street

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Mohamad hasan Nemati

**Position**

cardiac surgon

**Latest degree**

Subspecialist

**Other areas of specialty/work**

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Neda Reihanifard

**Position**

Cardiac perfusionist/ student

**Latest degree**

Master

**Other areas of specialty/work**

Cardiology

**Street address**

Anesthesiology Department, Faghihi Hospital, Zand Street

**City**

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**Postal code**

71896569487

**Phone**

+98 71 3620 3853

**Email**

nedaaa.reihanifard@gmail.com

## 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**

Undecided - It is not yet known if there will be 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**

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

**Clinical Study Report**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable