

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

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

arterteriosclerosis

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

venus blood sample

2

Description

Serum level of Troponin

Timepoint

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

Method of measurement

venus 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

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Chamran boulevard, Ordibehesht hospital

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2

Recruitment center

Name of recruitment center

Shiraz central hospital

Full name of responsible person

Mohamad Reza Khoshnood

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Younes Ghasemi

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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

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Person responsible for scientific inquiries

Contact

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Latest degree

Subspecialist

Other areas of specialty/work

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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