Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

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

Protocol summary

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
2019-01-06, 1397/10/16

Registrant information
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Maryam Tabibzadeh
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Iran (Islamic Republic of)
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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
Arhytmia

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
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7461477587
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+98 71 5336 2449
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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
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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
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Person responsible for scientific inquiries

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Specialist
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Person responsible for updating data

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Position
General physician

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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
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