

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Investigation of the changes in cardiac muscle damage marker and serum lactate in pateints undergoing cardiopumounary bypass using the del Nido cardioplegia versus Custodiol: A pilot study

Protocol summary

Summary

-Objective: to compare cardiac muscle damage marker and serum lactate levels in patients undergoing cardiopumounary bypass using the del Nido cardioplegia versus Custodiol. Study design: randomized, double-blinded, no use of placebo, single-center. Blinding will be done on patients and outcome assessors (nurses registering the clinical outcomes and laboratory personnel). -Population: -Inclusion criteria: patients undergoing coronary artery bypass and valve graft surgery, informed consent. -Exclusion criteria: diagnosed with inflammatory diseases before surgery, acute myocardial infarction, patient dissatisfaction in any part of the study, dialysis-requiring renal failure, ejection fraction less than 15%, second surgery, emergency patients, predictive pulmonary disease patients, cardiomyopathy patients. -Target sample size: 40 patients -Interventions: del Nido cardioplegia, Custodiol cardioplegia -Interventions time point: During cardiopumounary bypass -Primary outcome measures: Serum lactate, Cardiac Troponin I

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017083035991N1**
Registration date: **2017-10-25, 1396/08/03**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-10-25, 1396/08/03

Registrant information

Name

Mehdi Dehghan Firoozabadi

Name of organization / entity

Tehran Heart Center

Country

Iran (Islamic Republic of)

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Email address

mdfiroozabad@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2017-10-23, 1396/08/01

Expected recruitment end date

2017-12-22, 1396/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the changes in cardiac muscle damage marker and serum lactate in pateints undergoing cardiopumounary bypass using the del Nido cardioplegia versus Custodiol: A pilot study

Public title

A comparison of two methods to prevent cardiac muscle damage during cardiopulmonary bypass surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: patients undegoing coronary artery bypass and valve graft surgery, informed satisfaction.

Exclusion criteria: diagnosed inflammatory diseases before surgery, acute myocardial infarction, patient dissatisfaction, dialysis-requiring renal failure, ejection fraction less than 15%, second surgery, emergency patients, predictive pulmonary disease patients, cardiomyopathy patients.

Age
To 80 years old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: 40

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Blinding will be done on patients and outcome assessors (nurses registering the clinical outcomes and laboratory personnel). They will be unaware of the patients' allocation sequence.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of Tehran University of Medical Sciences

Street address

16 Azar St, Enghelab Sq, Tehran Province

City

Tehran

Postal code

Approval date

2017-09-17, 1396/06/26

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1396.3509

Health conditions studied

1

Description of health condition studied

Coronary artery bypass graft surgery

ICD-10 code

T82.9

ICD-10 code description

Unspecified complication of cardiac and vascular prosthetic device, implant and graft

Primary outcomes

1

Description

Cardiac Troponin I

Timepoint

Before operation, after operation and 24 hours after operation

Method of measurement

ng/ml using enzyme immunoassay

2

Description

Serum Lactate

Timepoint

Prior to the Coronary artery bypass graft surgery, Immediate post aortic declamping, At the entrance to the ICU, 6, 12, and 24 hours post entrance to the ICU

Method of measurement

Biochemical analyzer

Secondary outcomes

1

Description

Hemoglobin

Timepoint

Before operation, after operation and 24 hours after operation

Method of measurement

Hematology analyzer

2

Description

Hematocrit

Timepoint

Before operation, after operation and 24 hours after operation

Method of measurement

Hematology analyzer

3

Description

Platelet count

Timepoint

Before operation, after operation and 24 hours after operation

Method of measurement

Hematology analyzer

Intervention groups

1

Description

del Nido cardioplegia

Category

Treatment - Surgery

2

Description

Custodial cardioplegia

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran Heart Center

Full name of responsible person

Dr Mehdi Dehghan Firoozabadi

Street address

Surgery Department, Thran Heart Center, Nort Kargar
St Thran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-chancellor for Research, Tehran University of
Medical Sciences

Full name of responsible person

Dr. Mohammad Ali Sahraian

Street address

Qods St. Cross., Keshavars Blvd.

City

Thran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice-chancellor for Research, Tehran University of
Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran Heart Center

Full name of responsible person

Mohammad Javad Mehranbaniyan

Position

Anesthesiologist

Other areas of specialty/work

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Person responsible for scientific inquiries

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Position

Associate Professor

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Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran Heart Center

Full name of responsible person

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Position

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty