Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jul 2026

Evaluation the effects of vasodilator (nitroglycerin-TNG) in Cardioplegic Solution myocardial ischemia in patients treated with coronary artery bypass graft surgery in Chamran Hospital, Isfahan

Protocol summary

Study aim

Specific goals 1.Determination of serum troponin I changes before and after surgery in TNG and placebo groups 2.Determination of serum CK-MB changes before and after surgery in TNG and placebo groups 3.Determining the relationship between serum troponin I level before and after surgery in TNG and placebo groups with the number of grafts performed

Design

Clinical trial of control and intervention group and three randomized blind phases of phase 1-2 were performed on 44 patients

Settings and conduct

Operating room for patients with coronary artery bypass graft surgery with the addition of nitroglycerin to the cardioplegia solution, which is blinded on three sides and controlled by troponin and cpk tests before and after surgery.

Participants/Inclusion and exclusion criteria

Inclusion criteria 1) Consent of people to participate in the study; patients with coronary artery disease who will undergo CABG 2) EF more than 40% 3) Age between 35 to 70 years 4) Patients who are candidates for non-emergency surgery

Intervention groups

After obtaining written consent from patients, information about age, sex, medical history will be recorded and patients will be randomly divided into two groups receiving nitroglycerin and placebo. All individuals will be given information about the study protocol and moral approval will be obtained from Isfahan University of Medical Sciences for the study. All patients are advised to stop taking aspirin 7 days before surgery. Both groups of troponin I and CPK-MB samples will be checked before surgery.

Main outcome variables

Decreased ischemia, reperfusion in patients undergoing heart surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211225053517N1**
Registration date: **2022-02-11, 1400/11/22**
Registration timing: **registered_while_recruiting**

Last update: **2022-02-11, 1400/11/22**
Update count: **0**

Registration date

2022-02-11, 1400/11/22

Registrant information

Name

fatemeh amiridehnavi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-23, 1400/07/01

Expected recruitment end date

2022-03-20, 1400/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation the effects of vasodilator (nitroglycerin-TNG) in Cardioplegic Solution myocardial ischemia in patients treated with coronary artery bypass graft surgery in Chamran Hospital, Isfahan

Public title
Evaluation the effects of vasodilator (nitroglycerin-TNG) in Cardioplegic Solution myocardial ischemia in patients treated with coronary artery bypass graft surgery in Chamran Hospital, Isfahan

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
In this study, patients with Serener's disease who will undergo CABG. EF more than 40% Age between 35 and 70 years Candidates for non-emergency surgery Pump time between one to two hours Arrest time between 30 -100 minutes

Exclusion criteria:
Patients in cardiogenic shock and patients receiving known antioxidants such as captopril mannitol or allopurinol will be excluded from the study. Also unpredictable events that disrupt the normal surgical process, such as the use of an intra-aortic pump balloon and ECMO, cardiac arrest, The length of stay in the ICU for more than five days will result in the removal of the sample.

Age
From **35 years** old to **70 years** old

Gender
Both

Phase
1-2

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **44**

Randomization (investigator's opinion)
Randomized

Randomization description
Sampling method is a simple individual randomization method that was performed using SPSS statistical software and blind three-way.

Blinding (investigator's opinion)
Triple blinded

Blinding description
Lack of information of the participant evaluating the outcome and analyzing the data

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Isfahan University of Medical Sciences

Street address
No 110 Dastgerd Street, Shahid Safarian 2

City
Esfahan

Province
Isfehan

Postal code
8174854511

Approval date
2021-12-26, 1400/10/05

Ethics committee reference number
IR.MUI.MED.REC.1400.497

Health conditions studied

1

Description of health condition studied
Cardiovascular surgery

ICD-10 code
I25.1

ICD-10 code description
Atherosclerotic heart disease of native coronary artery

Primary outcomes

1

Description
Evaluation of changes in troponin and CPK in patients undergoing open heart surgery with nitroglycerin effect

Timepoint
Measurement of troponin and CPK before and after surgery

Method of measurement
Vidas device for troponin check and BT3000 device for CPK check

Secondary outcomes

empty

Intervention groups

1

Description
Addition of injectable nitroglycerin to weight-based cardioplegia solution

Category

Other

2

Description
Control group: Nitroglycerin-free cardioplegia solution
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Chamran Hospital
Full name of responsible person
Dr. Seyed Alireza Hosseini
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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
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Esfahan University of Medical Sciences
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
The result of the clinical trial will be published after the thesis is approved
When the data will become available and for how long
Access period starts 6 months after the results are published
To whom data/document is available
Researcher working in academic and scientific institutions
Under which criteria data/document could be used
For use in future studies
From where data/document is obtainable
Fatemeh Amiri Dehnavi
What processes are involved for a request to access data/document
Refer to the database of Isfahan University, thesis section
Comments