

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)

Phone

+98 31 3776 8614

Email address

amirif319@gmail.com

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.

AgeFrom **35 years** old to **70 years** old**Gender**

Both

Phase

1-2

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample sizeTarget 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

Isfahan

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

Street address

Salman Farsi St., Shahid Chamran Hospital

City

Esfahan

Province

Isfahan

Postal code

8166173414

Phone

+98 31 3260 0961

Fax

Email

chmrn-dabirkhaneh@mui.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Seyed Alireza Hosseini

Street address

Azadi Square, Hezar Jerib Street

City

Esfahan

Province

Isfahan

Postal code

8166173414

Phone

+98 31 3260 0961

Email

chmrn-dabikhaneh@mui.ca.ir

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

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Fatemeh Amiri

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

No. 110 Dastgerd St., Shahid Safarian Alley, 2 dead end,

City

Esfahan

Province

Isfahan

Postal code

8174854511

Phone

+98 31 3776 8614

Email

amirif319@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Seyed Alireza Hosseini

Position

surgery

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

Street address

Shahid Chamran Hospital

City

Esfahan

Province

Isfahan

Postal code

8166173414

Phone

+98 31 3260 0961

Email

hosseiny@med.mui.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Seyed Alireza Hosseini

Position

heart surgery

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

Street address

Mushtaq St., Shahid Chamran Hospital

City

esfahan

Province

Isfahan

Postal code

8166173414

Phone

+98 31 3260 0961

Email

hosseiny@med.mui.ac.ir

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