

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jun 2026

Studying the effect of ischemic postconditioning and controlled aortic root reperfusion on myocardial protection in CABG surgery with cardiopulmonary bypass

Protocol summary

Summary

Objective: Some degree of cardiac ischemia is seen in cardiac operation due to the decrease in coronary blood flow and re-perfusion injury. Myocardial infarction and decreased cardiac output are the main results of these injuries. In order to control the severity of these injuries, we will use a new type of conditioning strategy namely ischemic post conditioning in our study. Setting and conduct: Patients included in study are candidate for CABG, all will be undergoing cardiopulmonary. Then the aortic cross clamp will be applied and heart will be stopped. After completion of operation and just before releasing of cross clamp, coronary blood flow will be reestablished in three ways: controlled perfusion pressure, post conditioning and simultaneous technique. Inclusion criteria: Age 50-70; Left Ventricular EF more than 40 percent; Complete occlusion of LAD; No redo cardiac operation. Exclusion criteria: Concomitant operation; Aortic clamp time more than 100 minute; Cardiopulmonary bypass time more than 130 minute Intervention: Patients are divided in 3 groups: in first group, coronary perfusion with controlled perfusion pressure is applied, in second group we use intermittent clamping and de-clamping (each for 1 minute in three times), and in third group, we use both methods together simultaneously.. Main outcome measures: cardiac enzymes, oxidative stress markers and ejection fraction will be measured after operation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014121520324N1**

Registration date: **2015-02-07, 1393/11/18**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-02-07, 1393/11/18

Registrant information

Name

Naser Safaie

Name of organization / entity

Tabriz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2014-12-22, 1393/10/01

Expected recruitment end date

2015-03-21, 1394/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Studying the effect of ischemic postconditioning and controlled aortic root reperfusion on myocardial protection in CABG surgery with cardiopulmonary bypass

Public title

The effect of ischemic postconditioning on myocardial protection

Purpose

Prevention

Inclusion/Exclusion criteria

inclusion criteria: Age 50-70 years old; Ejection fraction more than 40 percent; Complete occlusion of LAD; No redo cardiac operation Exclusion criteria: concomitant operation; aortic clamp time more than 100 minute; CPB time more than 130 minute

Age

From **50 years** old to **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **51**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

-

Secondary trial Id

-

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

Street address

Daneshgah street

City

Tabriz

Postal code

Approval date

2014-10-09, 1393/07/17

Ethics committee reference number

93109

Health conditions studied

1

Description of health condition studied

Cardiovascular disease

ICD-10 code

I51.6

ICD-10 code description

Cardiovascular disease, unspecified

Primary outcomes

1

Description

Ejection Fraction

Timepoint

Before and 7 days after operation

Method of measurement

Echocardiography

2

Description

Cardiac dysrhythmia

Timepoint

After operation for 72 hours

Method of measurement

Cardiac monitoring and Electrocardiography

3

Description

oxidative stress enzymes

Timepoint

before starting of operation, Before starting coronary reperfusion, ten minute after reperfusion, 1st, 2nd, and 3rd days after operation

Method of measurement

Blood analyses

4

Description

Cardiac Enzymes

Timepoint

Before starting the operation, before starting coronary reperfusion, ten minute after reperfusion, 1st, 2nd, and 3rd days after operation

Method of measurement

biochemical analyses of blood

Secondary outcomes

1

Description

-

Timepoint

-

Method of measurement

Intervention groups

1

Description

In second group three repetitive episodes of 1 min ischemia separated by 1 min of reperfusion (at systemic pressure) will be applied on coronary artery Then the clamp will be released completely.

Category

Prevention

2

Description

In third group, controlled perfusion pressure and post conditioning will be applied together during reperfusion of coronary artery.

Category

Prevention

3

Description

All patients will undergo CABG operation with CPB assisted protocol, which will be conducted using a membrane oxygenator. Non pulsatile pump blood flow will be set at 2.4 times of body surface area and the body core temperature will be allowed to decline to 32 °c. In this setting, the cardioplegia solution is delivered via antegrade and retrograde routes for 4 minute with 150 ml.m2.min after aortic cross-clamp and repeated every 20 minutes. At the end of procedure and just before cross-clamp removal, reperfusion will be started in three groups as following: In first group, the coronary perfusion with controlled perfusion pressure of root aorta (30 mm Hg in first 3 minutes and then 50 mm Hg for last 7 minutes) will be applied.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Madani Heart Hospital

Full name of responsible person

Naser Safaie

Street address

Shahid Madani Heart Hospital, Daneshgah street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Tabriz University of Medical Sciences

Full name of responsible person

Mohammad Reza Rashidi

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Tabriz University of Medical Sciences, Daneshgah Street

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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

Vice chancellor for research, Tabriz 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

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Mohammad Ali Sheikhalzadeh

Position

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Web page address**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