

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

The effect of remote ischemic preconditioning (RIPC) on total antioxidant capacity (TAC) patients under coronary artery bypass grafting (CABG)

Protocol summary

Study aim

Determining and comparing the mean total antioxidant capacity (TAC) in patients in the two groups of remote ischemia induction (RIPC) and the control group

Design

A controlled clinical trial, with parallel groups, double-blinded, randomized, on 50 patients. Excel software rand function was used for randomization.

Settings and conduct

The project is carried out in the heart center of Tehran. The study is a clinical trial with two groups of remote ischemia preconditioning (RIPC) and control. Clinical and laboratory outcomes are performed by physicians and nurse assessors who are blind to the type of intervention. The patient is also unaware of the type of intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Candidate for coronary artery bypass grafting with cardiopulmonary bypass Normal upper limb examinations Not having surgical operations in the past three months Not having acute medical conditions during the last three months Exclusion criteria: Known inflammatory disorders Diabetes Liver disease Kidney disease Receiving vitamins C and/or E and/or other antioxidants

Intervention groups

- Intervention group under RIPC: ischemia by inflating the blood pressure cuff for 5 minutes and 5 minutes of reperfusion by deflating the cuff (4 times). - Control: No intervention will be performed.

Main outcome variables

Total antioxidant capacity, glutathione peroxidase activity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201014049022N1**

Registration date: **2020-11-15, 1399/08/25**

Registration timing: **registered_while_recruiting**

Last update: **2020-11-15, 1399/08/25**

Update count: **0**

Registration date

2020-11-15, 1399/08/25

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-22, 1399/08/01

Expected recruitment end date

2020-11-21, 1399/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of remote ischemic preconditioning (RIPC) on total antioxidant capacity (TAC) patients under coronary artery bypass grafting (CABG)

Public title

Improving oxidant effects following open heart surgery

Purpose

Basic science

Inclusion/Exclusion criteria

Inclusion criteria:

Candidate for coronary artery bypass grafting with cardiopulmonary bypass Normal upper limb examinations Not having surgical operations in the past three months Not having acute medical conditions during the last three months

Exclusion criteria:

Known inflammatory disorders Diabetes Liver disease Kidney disease Receiving vitamins C and/or E and/or other antioxidants

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **50**

More than 1 sample in each individual

Number of samples in each individual: **3**

1) The first venous blood sample will be drawn before the blood pressure cuff is closed in order to perform the desired intervention in relation to RIPC and in the control group will be performed at the corresponding time. 2) The second venous blood sample will be drawn after the CPB is completed. 3) The third venous blood sample will be taken 24 hours after ICU admission.

Randomization (investigator's opinion)

Randomized

Randomization description

The studied patients will be divided into two groups of intervention under RIPC and control. We use a simple randomization method for allocating patients into two groups. Each randomization unit is an individual that is assigned with a random number between zero and one using Excel software. Patients with a number greater than or equal to 0.5 are in the RIPC intervention group and the group with a number of less than 0.5 is in the control group. The anesthesiologist and the anesthesia nurse are aware of the group the patient is in and perform the intervention in the RIPC and control groups. The surgeon, the nurse recording the outcomes, and the laboratory expert who performs the laboratory tests have no knowledge of the study groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

The anesthesiologist and the anesthesia nurse are aware of the group the patient is in and perform the intervention in the RIPC and control groups. In the next stages, all interventions are similar in both groups, and the surgeon and the nurse recording the outcomes are not aware of the study group. Then, the samples drawn

by the anesthesia team are coded confidentially.

Therefore, the laboratory expert who performs the laboratory tests have no knowledge 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 Tehran University of Medical Sciences

Street address

Tehran University of Medical Sciences, Qods street cross., Keshavarz Blvd.

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1417653761

Approval date

2020-07-28, 1399/05/07

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1399.270

Health conditions studied

1

Description of health condition studied

Coronary artery bypass grafting

ICD-10 code

Z95.1

ICD-10 code description

Presence of aortocoronary bypass graft

Primary outcomes

1

Description

Total antioxidant capacity

Timepoint

After anesthesia induction, after cardiopulmonary bypass, 24 hours after intensive care unit admission

Method of measurement

With turbidimetry analysis

2

Description

Glutathione peroxidase activity assay

Timepoint

After anesthesia induction, after cardiopulmonary bypass, 24 hours after intensive care unit admission

Method of measurement

With turbidimetry analysis

Secondary outcomes**1****Description**

Troponin level

Timepoint

After anesthesia induction, after cardiopulmonary bypass, 24 hours after intensive care unit admission

Method of measurement

ELISA

2**Description**

Ejection fraction

Timepoint

Every 8 hours after intensive care unit admission

Method of measurement

Echocardiography

Intervention groups**1****Description**

Intervention group: inflation of the blood pressure cuff for 5 minutes and deflation for 5 minutes with 4 repeats

Category

Treatment - Other

2**Description**

Control group: no intervention

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Tehran Heart Center

Full name of responsible person

Mehdi Dehghani Firouzabadi

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Tehran Heart Center, North Karegar St., Jalal-e-Al-e-Ahmad cross.

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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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

Tehran 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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Farhad Gorjipour

Position

Perfusionist

Latest degree

Master

Other areas of specialty/work

Clinical Perfusion

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Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

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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

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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