Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 scienece
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.
City
Tehran
Province
Tehran
Postal code
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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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
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
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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