Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effect of Ischemic postconditioning on myocardial protection in patients undergoing coronary artery bypass graft surgery

Protocol summary

Study aim

Determine the effect of Ischemic postconditioning on myocardial protection in patients undergoing coronary artery bypass graft surgery

Design

A randomized parallel control group, open-label, phase 2 clinical trial

Settings and conduct

The study population is patients with an age range of 50 to 70 years With coronary atherosclerosis Candidate for CABG referred to Ayatollah Rouhani Hospital in Babol.After the initial assessment and Having entry conditions, They are randomly divided into three groups. before weaning from the pump, In IPost group repetitive brief episodes of opening and occluding the vascular grafts, In perfusion group,12 minutes after releasing the partial aortic clamp without occluding any vascular graft. in control group,weaning was done immediately after releasing the partial aortic clamp. After surgery,serum CPK-MB level will be measured

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 50-70, All patients with atherosclerosis are candidates for coronary artery bypass graft surgery, No redo cardiac operation, serum CPK of MB level less than 20, Receive informed consent Exclusion criteria: Underlying diseases such as kidney disorders, liver disorders

Intervention groups

Patients are divided into three groups. In IPost group and before weaning from the pump, repetitive brief episodes of opening and occluding the vascular grafts were created using bulldog clamp. Each episode was 3 minutes long and the entire process lasted 12 minutes. In the perfusion group, weaning was done 12 minutes after releasing the partial aortic clamp without occluding any vascular graft. Lastly in the control group, weaning was done immediately after releasing the partial aortic clamp

Main outcome variables

serum CPK-MB level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161021030410N4**
Registration date: **2021-09-09, 1400/06/18**
Registration timing: **registered_while_recruiting**

Last update: **2021-09-09, 1400/06/18**
Update count: **0**

Registration date

2021-09-09, 1400/06/18

Registrant information

Name

Ghasem Faghanzadeh Ganji

Name of organization / entity

Babol University of Medical Science

Country

Iran (Islamic Republic of)

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+98 11 3223 8308

Email address

gh.faghanzadeh@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-05, 1400/06/14

Expected recruitment end date

2021-11-21, 1400/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of the effect of Ischemic postconditioning on myocardial protection in patients undergoing coronary artery bypass graft surgery

Public title
The effect of ischemic postconditioning on myocardial protection

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Age 50-70 Serum CPK levels of MB less than 20 before surgery All patients with atherosclerosis are candidates for coronary artery bypass graft surgery No redo cardiac operation Receive informed consent

Exclusion criteria:
Underlying diseases such as kidney disorders, liver disorders

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

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **150**

Randomization (investigator's opinion)
Randomized

Randomization description
The patients will be randomly divided into 3 groups of 50 subjects with six blocks and an allocation ratio of 1:1:1. The participants allocation sequence in three groups perform with a Randomizer software. Opaque sealed sequentially numbered envelops use for allocation concealment.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Babol University of Medical Sciences

Street address
Babol University of Medical Sciences, Ganjafrooz Street, Babol, Mazandaran, Iran

City
Babol

Province
Mazandaran

Postal code
4716681451

Approval date
2020-04-04, 1399/01/16

Ethics committee reference number
IR.MUBABOL.REC.1399.006

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
CPK-MB Enzyme

Timepoint
Before operation, immediatelly after operation, 6 hours after operation, 12 hours after operation and 24 hours after operation

Method of measurement
Serology

Secondary outcomes

empty

Intervention groups

1

Description
Control group: routine after heparin and cannulation of the aorta and right atrium and start the pump, aortic clamping and injection cardioplegin the aortic root and inducing arrest of the heart, anastomosis distal to the vascular coronary and after turning clamp of perfect for the partial, proximal anastomosis will be performed.In this group, immediately after removing the partial aortic clamp, the pump will be removed.

Category
Prevention

2

Description
Intervention group: In perfusion group, 12 minutes after

removal of the aortic partial clamp exits the pump without vascular grafts close by bulldog.

Category

Prevention

3

Description

Intervention group: In Ipost group before leaving the pump, 3 minutes after removal of the aortic partial clamp, vascular grafts are closed by bulldogs for 3 minutes. again reopen these bulldogs for three minutes and close again for another 3 minutes (overall for 12 minutes after removing the aortic partial clamp) bulldogs are removed. then patient exits of pump.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Babol Ayatollah Rouhani Hospital

Full name of responsible person

Dr. Ghasem Faghanzadeh Ganji

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Babol University of Medical Sciences, Ganjafrooz Street, Babol, Mazandaran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Dr. Reza Ghadimi

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Babol 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

Babol University of Medical Sciences

Full name of responsible person

Dr. Ghasem Faghanzadeh Ganji

Position

Associated professor

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
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Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available