

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Jun 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)

##### Phone

+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 envelopes 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, immediately 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

**Street address**

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

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<http://www.mubabol.ac.ir/>

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

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rezaghadimi@yahoo.com

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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 updating data**

**Contact**

**Name of organization / entity**

Babol University of Medical Sciences

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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**

**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