

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Evaluation of the effect of Remote Ischemic Pre Conditioning on post operative atrial fibrillation in patients undergoing coronary artery bypass graft surgery

Protocol summary

Study aim

Evaluation of the effect of Remote Ischemic Pre Conditioning on post operative atrial fibrillation in patients undergoing coronary artery bypass graft surgery

Design

A randomized clinical trial without control group, with parallel groups, without blindness that, 80 patients randomly divided into two groups of 40 subjects with block sizes of 4 and 6.

Settings and conduct

The study population was patients aged 40-80 years referred to Ayatollah Rouhani Hospital in Babol. Patients were randomly divided into two intervention groups using a random number table and the free website WWW.randomization.com.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with coronary artery disease are candidates for coronary artery bypass grafting
Exclusion Criteria: Chronic lung disease, Liver disease, kidney disease, Emergency surgery and Thyroid diseases

Intervention groups

Intervention group: The pressure indicator cuff closes around the right arm. The pressure indicator cuff is filled alternately in three shifts of 5 minutes up to 200 mm Hg, which are separated by 5-minute rest intervals, during which the cuff breaks completely. Control group: The pressure indicator cuff is closed around the right arm. The pressure indicator cuff is never filled and only closes around the right arm for 30 minutes.

Main outcome variables

Atrial fibrillation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20101213005381N14**

Registration date: **2021-03-07, 1399/12/17**

Registration timing: **registered_while_recruiting**

Last update: **2021-03-07, 1399/12/17**

Update count: **0**

Registration date

2021-03-07, 1399/12/17

Registrant information

Name

Nadia Banihashem

Name of organization / entity

Babol University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 22 38296

Email address

nbanihashem@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-08, 1399/11/20

Expected recruitment end date

2021-08-21, 1400/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of Remote Ischemic Pre Conditioning on post operative atrial fibrillation in

patients undergoing coronary artery bypass graft surgery

Public title

Evaluation of postoperative atrial fibrillation in patients with heart surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with coronary artery disease are candidates for coronary artery bypass grafting

Exclusion criteria:

Chronic lung disease Liver disease kidney disease
Emergency surgery Thyroid diseases

Age

From **40 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

The patients randomly divided into two groups of 40 subjects with four and six blocks and an allocation ratio of 1: 1. The free website WWW.randomization.com was used to generate the allocation sequence. The obtained sequence was written on separate sheets and placed in sealed envelopes and given to the main researcher for study.

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

Daneshgah Square, Ganjafrooz Avenue

City

Babol

Province

Mazandaran

Postal code

47176-41367

Approval date

2020-12-05, 1399/09/15

Ethics committee reference number

IR.MUBABOL.REC.1399.409

Health conditions studied

1

Description of health condition studied

Atrial fibrillation

ICD-10 code

I48

ICD-10 code description

Atrial fibrillation and flutter

Primary outcomes

1

Description

Atrial fibrillation after CABG

Timepoint

From the end of surgery until 72 hours after surgery

Method of measurement

Heart monitoring

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The pressure indicator cuff closes around the right arm. The pressure indicator cuff is filled alternately in three shifts of 5 minutes up to 200 mm Hg, which are separated by 5-minute rest intervals, during which the cuff breaks completely.

Category

Diagnosis

2

Description

Control group: The pressure indicator cuff is closed around the right arm. The pressure indicator cuff is never filled and only closes around the right arm for 30 minutes.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Rouhani Hospital

Full name of responsible person

Nadia Banihashem

Street address

Daneshgah Square, Ganjafrooz Avenue, Ruhani Hospital

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

Babol University of Medical Sciences

Full name of responsible person

Reza Ghadimi

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Daneshgah Square, Ganjafrooz Avenue, Vice-chancellor Of Research,

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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

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

Nadia Banihashem

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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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

There is still no plan for its puplish

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