

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

The effect of remote ischemic preconditioning on kidney and cardiac injury after CABG

Protocol summary

Summary

Objectives: The effect of remote ischemic preconditioning on kidney and cardiac injury after CABG
Design: This is a single center, randomized, double-blind, parallel-group, controlled clinical trial. Setting and conduct: According to the sample size, 100 patients undergoing CABG in Mazandaran Heart Center will randomly divide into two equal intervention and control groups. **Participants:** We include non-emergency on-pump first time CABG patients with EF higher than 35% and exclude under 18 years of age; CABG with valve surgery; pregnancy; advanced liver disease (INR >2.0); severe renal impairment (Creatinine clearance <50 ml/min); respiratory failure (O2 Sat <90 %); acute myocardial infarction up to 14 days before surgery; advanced peripheral vascular disease affecting the lower limbs; drug therapy with sulfonamide or Nicorandil. **Intervention:** After induction of anesthesia and before skin incision, remote ischemic preconditioning will perform by 3 cycles of 5-minute inflation of an upper thigh tourniquet to 200mmHg (or at least to a pressure 50mmHg higher than the systolic arterial pressure), followed by 5-minute reperfusion with the tourniquet deflated. For the control group, the tourniquet will place on the upper thigh and left uninflated for 30 min. **Variables:** Acute kidney injury and Serum Troponin I

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138903123646N3**

Registration date: **2016-02-24, 1394/12/05**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-02-24, 1394/12/05

Registrant information

Name

Mahmoud Nouraei

Name of organization / entity

Mazandaran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Mazandran university of Medical sciences research council

Expected recruitment start date

2014-03-01, 1392/12/10

Expected recruitment end date

2015-02-01, 1393/11/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of remote ischemic preconditioning on kidney and cardiac injury after CABG

Public title

The effect of remote ischemic preconditioning on kidney and cardiac injury after CABG

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: non-emergency on-pump first time

CABG; EF higher than 35% Exclusion criteria: under 18 years of age; CABG with valve surgery; pregnancy; advanced liver disease (INR >2.0); severe renal impairment (Creatinine clearance <50 ml/min); respiratory failure (O2 Sat <90 %); acute myocardial infarction up to 14 days before surgery; advanced peripheral vascular disease affecting the lower limbs; drug therapy with sulfonamide or Nicorandil.

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

N/A

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mazandaran University of Medical Sciences

Street address

Mazandaran University of Medical Sciences, Moallem Square

City

Sari

Postal code

4818813771

Approval date

2013-01-23, 1391/11/04

Ethics committee reference number

91-171

Health conditions studied

1

Description of health condition studied

Atherosclerotic heart disease

ICD-10 code

I25.1

ICD-10 code description

Atherosclerotic heart disease

Primary outcomes

1

Description

Acute kidney injury

Timepoint

preoperatively and 6, 12, 24 and 48 h postsurgery

Method of measurement

Acute Kidney Injury Network criteria

2

Description

Serum Troponin I

Timepoint

0, 6, 12, 24, 48

Method of measurement

Laboratory kit

Secondary outcomes

1

Description

Atrial fibrillation

Timepoint

After surgery

Method of measurement

Data collecting form

2

Description

Dialysis

Timepoint

Before and 6, 12, 24 and 48 hours after surgery

Method of measurement

Data collecting form

3

Description

Serum creatinine

Timepoint

Before and 6, 12, 24 and 48 hours after surgery

Method of measurement

laboratory kit

4

Description

Serum CRP

Timepoint

Before and 6, 12, 24 and 48 hours after surgery

Method of measurement

Laboratory kit

5

Description

Inotrope requirement

Timepoint

6, 12, 24 and 48 hours after surgery

Method of measurement

Data collecting form

6

Description

Ventilator time

Timepoint

After surgery

Method of measurement

Data collecting form

7

Description

Length of ICU stay

Timepoint

After surgery

Method of measurement

Data collecting form

8

Description

In-hospital mortality

Timepoint

After surgery

Method of measurement

Data collecting form

Intervention groups

1

Description

After induction of anesthesia and before skin incision, remote ischemic preconditioning will perform by 3 cycles of 5-minute inflation of an upper thigh tourniquet to 200mmHg (or at least to a pressure 50mmHg higher than the systolic arterial pressure), followed by 5-minute reperfusion with the tourniquet deflated

Category

Treatment - Devices

2

Description

After induction of anesthesia and before skin incision, the tourniquet will place on the upper thigh and left uninflated for 30 min.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Mazandran Heart Center

Full name of responsible person

Dr. Seyed Mahmoud Nouraei

Street address

Mazandaran Heart center, Artesh Blvd

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Mazandaran University of Medical Sciences

Full name of responsible person

Ahmad Ali Enayati, MD

Street address

Mazandaran University of Medical Sciences, Moallem Square , Sari, Iran

City

Sari

Grant name

Grant code / Reference number

91-171

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

Yes

Title of funding source

Vice chancellor for research of Mazandaran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Mojtaba Shokri

Position

Cleric in Education Department of Fatemeh Zahra Hospital

Other areas of specialty/work

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Person responsible for scientific inquiries

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MD, FRCS, Associate Professor of Cardiothoracic Surgery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty