

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Studing the effect of remote ischemic preconditioning on blood Troponin I level in patients undergoing open cardiosurgery

Protocol summary

Summary

The aim of this study is to identify the effect of remote ischemic preconditioning on troponin I. The individuals will be randomized using sealed envelopes and the study will be double blind and unicentral clinical trial. For the purpose of this study 28 patients will be chosen and will be divided to two equal groups (14 case and 14 control). Including criteria: ASA 2 or 3, normal troponin I level, no recent myocardial infarction, ejection fraction more than 35%, no renal and hepatic dysfunction, no arterio-venous fistula, no lymph edema. Excluding criteria: ASA 4 or more, elevated baseline troponin I, myocardial infarction in recent 4 weeks, ejection fraction less than 35%, renal dysfunction, arterio venous fistula, lymph edema, severe endocrine or hepatic dysfunction. At first, two milliliters of patient's arterial blood will be sent to laboratory for measurement of baseline troponin I. In case group after induction of anesthesia and intubation, pneumatic tourniquet will inflate for 5 minutes up to 200 mmHg on the upper arm and deflate for 5 minutes. This cycle will be repeated two times. Second and third samples will be sent to laboratory at 6, 24 hours after the first sample. After remote ischemic preconditioning troponin I level, intubation time, inotropic requirement and patient hemodynamic during and after surgery will be evaluated. In control group after induction of anesthesia and intubation pneumatic tourniquet will be set on the right upper limb but will not be inflated and blood samples will be sent to laboratory like case group.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016120431226N1**

Registration date: **2017-01-18, 1395/10/29**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-01-18, 1395/10/29

Registrant information

Name

Mohsen Moaddeli

Name of organization / entity

Ahwaz University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 61336754360

Email address

moaddeli.m@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

No financial source

Expected recruitment start date

2016-12-21, 1395/10/01

Expected recruitment end date

2017-01-04, 1395/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Studing the effect of remote ischemic preconditioning on blood Troponin I level in patients undergoing open cardiosurgery

Public title

Effect of ischemia in cardio surgery patients

Purpose

Treatment

Inclusion/Exclusion criteria

Including criteria: ASA 2,3; normal troponin one level; no recent myocardial infarction; ejection fraction more than 35%; no renal and hepatic dysfunction; no arterio-venous fistula; no lymph edema. Excluding criteria: ASA 4 or more; elevated baseline troponin I; myocardial infarction in recent 4 weeks; ejection fraction less than 35%; renal dysfunction; arterio-venous fistula; lymph edema; severe endocrine or hepatic dysfunction.

Age

From **19 years** old to **69 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **28**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double 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 Ahwaz University of Medical Science

Street address

Golestan Blv, Ahwaz University of Medical Science

City

Ahwaz

Postal code

61357-15794

Approval date

2016-11-26, 1395/09/06

Ethics committee reference number

IR.AJUMS.REC.1395.501

Health conditions studied

1

Description of health condition studied

coronary disease/valvular disease

ICD-10 code

-

ICD-10 code description

-

Primary outcomes

1

Description

Troponin I

Timepoint

time0, 6 and 24 hour after intervention

Method of measurement

quantitative troponin kit

Secondary outcomes

1

Description

intubation time

Timepoint

6 hour, 24 hour

Method of measurement

clock

2

Description

systolic and diastolic pressure

Timepoint

time 0,time 6,time 24

Method of measurement

Sphygmomanometer

Intervention groups

1

Description

Intervention group: after induction of anesthesia and intubating the patient under open cardiac surgery, pneumatic cuff will be fastened on patient's arm and will be inflated up to 200 mmHg and kept in this condition for 5 minutes and then deflated and the arm will rest for 5 minutes .This procedure will be repeated two times more.

Category

Treatment - Other

2

Description

Control group: The pneumatic tourniquet cuff will only be fastened and will not be inflated.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Cardiosurgery ward of Golestan hospital

Full name of responsible person

Mohsen Moaddeli

Street address

Golestan hospital, Farvardin st, Golestan blv

City

Ahwaz

Ahwaz

Postal code

61357-15794

Phone

+98 61 3336 7543

Fax

+98 61 3336 7543

Email

moaddeli.m@ajums.ac.ir;

moadelimohsen@yahoo.com

Web page address

www.ajums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Ahwaz University of Medical Science

Full name of responsible person

Mohsen Moaddeli

Street address

Vice Chancellor for research of Ahwaz University of Medical Science

City

Ahwaz

Grant name

-

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for research of Ahwaz University of Medical Science

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

Ahwaz University of Medical Science

Full name of responsible person

Mohsen Moaddeli

Position

Anesthesiology resident

Other areas of specialty/work

Street address

Golestan hospital, Farvadin St, Golestan Blv

City

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahwaz University of Medical Science

Full name of responsible person

Mohsen Moaddeli

Position

Anesthesiology resident

Other areas of specialty/work

Street address

Golestan hospital, Farvardin St, Golestan Blv

City

Ahwaz

Postal code

61357-15794

Phone

+98 61 3336 7543

Fax

+98 61 3336 7543

Email

moaddeli.m@ajums.ac.ir;

moadelimohsen@yahoo.com

Web page address

www.ajums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Ahwaz University of Medical Science

Full name of responsible person

Mohsen Moaddeli

Position

Anesthesiology resident

Other areas of specialty/work

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Fax

+98 61 3336 7543

Email

moaddeli.m@ajums.ac.ir;

moadelimohsen@yahoo.com

Web page address

www.ajums.ac.ir

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