Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of induced muscle ischemia on prevention of acute kidney injury based on serum cystatin-c in admitted patients undergoing coronary angiography

Protocol summary

Study aim
Evaluation of induced muscle ischemia on prevention of acute kidney injury based on serum cystatin-C in admitted patients undergoing coronary angiography

Design
A randomized (simple randomization), double-blinded, clinical trial with a parallel group design of 140 patients referred to Shahid Mohammadi Hospital who need coronary angiography.

Settings and conduct
patients will be randomly divided into two groups by using simple randomization method. in both groups, the pressure cuff is closed to the patient and in the treatment group, it is inflated up to 200 mm Hg and in the control group up to 20 mm Hg. Then the patients will undergo coronary angiography at Bandar-abbas Shahid mohammadi Hospital.In order to blind the analyzer, the persons responsible for executing Ischemic Preconditioning and data collection are different from the outcome assessors.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age equal to or greater than 18 years; patients who don't use nephrotoxic drugs 72 hours before angiography; ejection fraction> 50%; no cardiogenic shock or recent cardiac infarction. Exclusion criteria: patients who did not have consent to participate in the study; patients with renal dysfunction (GFR <60) based on KDIGO criteria; pregnant women; patients needing an emergency angiography.

Intervention groups
Intervention group: Remote Ischemic Preconditioning (RIPC) will be performed via the automated delivery of three cycles of 200 mm/Hg blood pressure cuff inflation for 5 min followed by cuff deflation for 5 min in the upper arm. Control group: sham-RIPC will be done by three cycles of upper-limb pseudo ischemia (5-min cuff inflation to a pressure of 20 mmHg and 5-min cuff deflation).

Main outcome variables
Serum Creatinine; Estimated glomerular filtration rate; Serum Cystatin-C; Acute Kidney Injury according to the 2012 Kidney Disease: Improving Global Outcomes criteria.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180924041113N1**
Registration date: **2018-10-30, 1397/08/08**
Registration timing: **retrospective**

Last update: **2018-10-30, 1397/08/08**
Update count: **0**

Registration date
2018-10-30, 1397/08/08

Registrant information

Name
Azadeh Moradkhani

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 76 3375 4950

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-11-06, 1396/08/15

Expected recruitment end date

2018-07-23, 1397/05/01

Actual recruitment start date

2017-11-06, 1396/08/15

Actual recruitment end date

2018-06-20, 1397/03/30

Trial completion date

2018-06-20, 1397/03/30

Scientific title

Evaluation of induced muscle ischemia on prevention of acute kidney injury based on serum cystatin-c in admitted patients undergoing coronary angiography

Public title

Preventive Effect of induced muscle ischemia on acute kidney injury

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age equal to or greater than 18 years Hospitalized patients requiring angiography Patients who don’t use nephrotoxic drugs 72 hours before angiography Ejection fraction (EF) > 50% Patients without cardiogenic shock or recent cardiac infarction

Exclusion criteria:

Patients who did not have consent to participate in the study Patients with renal dysfunction (glomerular filtration rate (GFR) <60) based on KDIGO criteria Pregnant women Patients needing an emergency angiography

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **140**

Actual sample size reached: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

Method of randomization: simple, Unit of randomization: individual, Tools used in randomization: table of random numbers, Patients are randomly divided into two groups of case and placebo by the table derived from Random Allocation software and they are placed in their respective group specified by the software in the order of inclusion in the study. (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC533876/)

Blinding (investigator's opinion)

Double blinded

Blinding description

In order to blind the patient, in both groups, the pressure cuff is closed to the patient and in the treatment group, it is inflated up to 200 mm Hg and in the control group up to of 20 mm Hg. In order to blind the analyzer, the persons responsible for executing Remote Ischemic Preconditioning (RIPC) and data collection are different from the outcome assessors.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hormozgan University of Medical Sciences

Street address

Ethical committee of Hormozgan University of Medical Sciences, Shahid Mohammadi Hospital, Kuye Farhangian, Islamic Republic blvd

City

Bandare-abbas

Province

Hormozgan

Postal code

7919915519

Approval date

2017-11-05, 1396/08/14

Ethics committee reference number

HUMS.REC.1396.42

Health conditions studied

1

Description of health condition studied

Renal dysfunction

ICD-10 code

N17

ICD-10 code description

Acute kidney failure

Primary outcomes

1

Description

Serum Creatinine

Timepoint

Before intervention and after intervention daily for 2 days

Method of measurement

AutoAnalyzer

2

Description

Serum Cystatin-C

Timepoint

Before intervention and 24 hours after intervention

Method of measurement

The enzyme-linked immunosorbent assay (ELISA) kit

3

Description

Estimated glomerular filtration rate (eGFR)

Timepoint

Before intervention and after intervention daily for 2 days

Method of measurement

Glomerular filtration rate Equation

4

Description

Acute Kidney Injury (AKI)

Timepoint

After intervention daily for 2 days

Method of measurement

The 2012 Kidney Disease: Improving Global Outcomes (KDIGO) criteria

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Remote Ischemic Preconditioning (RIPC) performed via the automated delivery of three cycles of 200 mm Hg blood pressure cuff inflation for 5 min followed by cuff deflation for 5 min on the non-dominant arm

Category

Prevention

2

Description

Control group: sham-RIPC (Remote Ischemic Preconditioning) intervention induced by three cycles of upper-limb pseudo ischemia (low pressure: 5-min blood pressure cuff inflation to a pressure of 20 mmHg and 5-min cuff deflation)

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Cardiac centre of Shahid Mohammadi Hospital

Full name of responsible person

Azadeh Moradkhani

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Shahid Mohammadi Hospital, Islamic Republic blvd.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bandare-abbas University of Medical Sciences

Full name of responsible person

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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

Bandare-abbas 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

Bandare-abbas University of Medical Sciences

Full name of responsible person

Azadeh Moradkhani

Position

Resident of Internal Medicine

Latest degree
Medical doctor

Other areas of specialty/work
Internal Medicine

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
All the patient's data can be shared with privacy in regard to patients name

When the data will become available and for how long
Start accessing 6 months after publishing the results.

To whom data/document is available
For scholars working in academic centers.

Under which criteria data/document could be used
It can be analyzed and printed by other people by mentioning the source.

From where data/document is obtainable
dr. Azadeh Moradkhani,00989121995157,azadeh.moradkhani@yahoo.com

What processes are involved for a request to access data/document
Upon authentication, data is provided to the individual.

Comments