Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of protective effect of induced muscle ischemia on contrast induced acute kidney injury (CI-AKI) after cardiac angiography or Percutaneous Coronary Intervention (PCI) in cardiac patient admitted at Shahid Mohammadi hospital in 2017-2018

Protocol summary

Study aim

Evaluation of protective effect of induced muscle ischemia on contrast induced acute kidney injury (CI-AKI) after cardiac angiography or Percutaneous Coronary Intervention (PCI) in cardiac patients admitted to Shahid Mohammadi hospital in 2017-2018

Design

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

Settings and conduct

patients will be randomly divided into two groups of seventy. For randomization, we will use simple randomization method. The location is the cardiac center at Shahid Mohammadi hospital. Patients and outcomes analyzer are blinded.

Participants/Inclusion and exclusion criteria

People over 18 years old who will undergo elective angiography, no ill or pregnant, no renal dysfunction before the intervention.

Intervention groups

Eligible patients will be randomized to the RIPC treatment group or the control group. In the treatment group, 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 upper arm. In the control group, sham-RIPC intervention will be done by three cycles of upper-limb pseudo ischemia (low pressure: 5-min cuff inflation to a pressure of 20 mmHg and 5-min cuff deflation).

Main outcome variables

Serum Creatinine and Estimated glomerular filtration rate (eGFR); Urine Neutrophil gelatinase-associated lipocalin (NGAL); Acute Kidney Injury (AKI) according to the 2012 Kidney Disease: Improving Global Outcomes (KDIGO) criteria.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180820040838N1**
Registration date: **2018-10-01, 1397/07/09**
Registration timing: **retrospective**

Last update: **2018-10-01, 1397/07/09**
Update count: **0**

Registration date

2018-10-01, 1397/07/09

Registrant information

Name

Sanaz Soleymani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-11-21, 1395/09/01

Expected recruitment end date

2017-11-22, 1396/09/01

Actual recruitment start date

2016-11-21, 1395/09/01

Actual recruitment end date

2017-09-21, 1396/06/30

Trial completion date

2017-09-21, 1396/06/30

Scientific title

Evaluation of protective effect of induced muscle ischemia on contrast induced acute kidney injury (CI-AKI) after cardiac angiography or Percutaneous Coronary Intervention (PCI) in cardiac patient admitted at Shahid Mohammadi hospital in 2017-2018

Public title

Effect of induced muscle ischemia on kidney injury

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age equal or greater than 18 years Hospitalized patients requiring angiography or PCI

Exclusion criteria:

Patients who did not have consent to participate in the study Patients with renal dysfunction (GFR <60) based on KDIGO criteria Pregnant patients Patients who used nephrotoxic drugs 72 hours before angiography or PCI Patients who needed an emergency angiography or PCI Patients with cardiogenic shock, recent cardiac infarction or EF < 50%

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

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 such as table of random numbers.

Blinding (investigator's opinion)

Double blinded

Blinding description

This is a double-blind study in which patients and outcomes analyzer are blinded. In order to blind the patient, in both groups, it is said that RIPC protocol is being used. In order to blind the analyzer, the persons responsible for executing RIPC and data collection are different from the outcome assessors.

Placebo

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, Islamic Republic blvd.

City

Bandare-abbas

Province

Hormozgan

Postal code

7916613885

Approval date

2017-11-05, 1396/08/14

Ethics committee reference number

HUMS.REC.1396.43

Health conditions studied

1

Description of health condition studied

Renal dysfunction

ICD-10 code

N17

ICD-10 code description

Acute renal failure

Primary outcomes

1

Description

Serum Creatinine

Timepoint

Before intervention and after intervention daily for 2 days

Method of measurement

AutoAnalyzer

2

Description

Urine Neutrophil gelatinase-associated lipocalin (NGAL)

Timepoint

Before intervention and 6 hours 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
Modification of diet in renal diseases (MDRD) GFR Equation

4

Description
Acute Kidney Injury (AKI)
Timepoint
After intervention
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
Sanaz Soleymani
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Sponsors / Funding sources

1

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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
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Position
Resident of 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. Sanaz Soleymani, +98 917 367 9262, sanazsoleymani9262@gmail.com.
What processes are involved for a request to access data/document
Upon authentication, data is provided to the individual.
Comments