

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 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)

##### Phone

+98 76 3375 4950

##### Email address

azadeh.moradkhani@yahoo.com

##### 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

**Street address**

Shahid Mohammadi Hospital, Islamic Republic Blvd.

**City**

Bandare-Abbas

**Province**

Hormozgan

**Postal code**

7916613885

**Phone**

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mail@hums.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Bandare-abbas University of Medical Sciences

**Full name of responsible person**

Dr. Teymour Aghamolayi

**Street address**

Deputy of research and technology, Shahid Mohammadi Hospital, Islamic republic Blvd

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**Phone**

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**Email**

research@hums.ac.ir

**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

**Street address**

Shahid Mohammadi Hospital, Kuy e Farhangian,  
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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Bandare-abbas University of Medical Sciences

**Full name of responsible person**

Hamidreza Samimagham

**Position**

Nephrologist

**Latest degree**

Subspecialist

**Other areas of specialty/work**

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## Person responsible for updating data

**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

**Street address**

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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**