

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 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)

##### Phone

+98 76 3333 3158

##### Email address

soleimani@hormozgan.ac.ir

##### 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

##### **Street address**

Shahid Mohammadi Hospital, Islamic Republic blvd.

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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**

Hormozgan University of Medical Sciences

##### **Street address**

Shahid Mohammadi Hospital, Islamic republic Blvd

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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**

Sanaz Soleymani

##### **Position**

Resident of Internal Medicine

##### **Latest degree**

Medical doctor

##### **Other areas of specialty/work**

Internal Medicine  
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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 Samimaghani  
**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**  
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**Position**  
Resident of Internal Medicine

**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
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sanazsoleymani9262@gmail.com

## 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