

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

Remote Ischemic preconditioning effect for prevention of contrast-induced nephropathy in patients with coronary angiography/angioplasty

Protocol summary

Study aim

Contrast-induced nephropathy reduction by remote ischemic preconditioning

Design

100 patients in the intervention group 45 minutes before angiography /angioplasty under induction ischemia with blood pressure cuff in the elbow area by inflating the cuff 50 mm Hg above systolic pressure in 5-minute for 4 cycles and emptying the cuff for 5 minutes between cycles with standard treatment And in the control group, 100 patients were randomly compared with standard creatinine only with standard treatment and inflated cuff pressure gauge of 10 mm Hg less than systolic pressure for contrast induced nephropathy with creatinine and eGFR baseline and 48 hours later.

Settings and conduct

100 patients in the intervention group 45 minutes before angiography / angioplasty under induction ischemia with blood pressure cuff in the elbow area by inflating the cuff 50 mm Hg above systolic pressure in 5-minute for 4 cycles and emptying the cuff for 5 minutes between cycles with standard treatment And in the control group, 100 patients were randomly compared with standard creatinine only with standard treatment and inflated cuff pressure gauge of 10 mm Hg less than systolic pressure in Dr. Shariati Hospital in Tehran. If creatinine increases more than 0.5 mg /dL or eGFR decreases, more than 25% of contrast-induced nephropathy is considered.

Participants/Inclusion and exclusion criteria

Age over 18 years Non-dialysis Creatinine greater than 1.4 mg/dl or eGFR less than 60 cc/min Conscious consent of the intervention type Possibility of intervention

Intervention groups

1: Patients with creatinine \geq 1.4 mg/dl or eGFR <60 ml/min with standard treatment and induction ischemia with blood pressure cuff 2: Patients with creatinine \geq 1.4 mg/dl or eGFR <60 ml/min with standard treatment without induction ischemia with blood pressure cuff

Main outcome variables

Determination of incidence of contrast induced nephropathy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200617047814N1**

Registration date: **2020-07-04, 1399/04/14**

Registration timing: **registered_while_recruiting**

Last update: **2020-07-04, 1399/04/14**

Update count: **0**

Registration date

2020-07-04, 1399/04/14

Registrant information

Name

Seyed shafi shafipoor

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4044 8126

Email address

milad.shafipoor@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-21, 1399/04/01

Expected recruitment end date

2020-07-22, 1399/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Remote Ischemic preconditioning effect for prevention of contrast-induced nephropathy in patients with coronary angiography/angioplasty

Public title

Remote Ischemic preconditioning effect for prevention of contrast-induced nephropathy

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Cr > 1.4mg/dl or eGFR < 60 cc/min Informed consent

Exclusion criteria:

hemodialysis or Peritoneal dialysis

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

Patient block randomization is performed using the website www.randomization.com, and patient codes are generated with envelope letters in which the data is not clear, and each of the random questions generated is recorded on a single card and the card is inserted into the packet.

Blinding (investigator's opinion)

Double blinded

Blinding description

In the method, none of the patients and angiography/angioplasty operators and researcher will be aware of patient coding and grouping. The clinical caregiver performs the intervention in the intervention group.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Tehran university of medical sciences

Street address

pour sina Ave

City

Tehran

Province

Tehran

Postal code

1417653911

Approval date

2020-03-17, 1398/12/27

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1399.002

Health conditions studied**1****Description of health condition studied**

Contrast induced nephropathy

ICD-10 code

N99.0

ICD-10 code description

Postprocedural (acute) (chronic) kidney failure

Primary outcomes**1****Description**

Cratinine

Timepoint

Before the procedure and 48 hours after the procedure

Method of measurement

blood test: based on mg/dl

2**Description**

eGFR

Timepoint

Before the procedure and 48 hours after the procedure

Method of measurement

blood test: calculated by cockroft furmola

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: In the intervention group, 45 minutes before angiography/angioplasty under induction ischemia with blood pressure cuff in the elbow area by inflating the cuff 50 mm Hg above systolic pressure in 5-minute for 4 cycles and 5-minute emptying between cycles with hydration. Standard treatment (hydration) is performed for all patients in the intervention and control

group. If creatinine increases more than 0.5 mg / dL or eGFR decreases, more than 25% of contrast-enhanced nephropathy is considered.

Category

Prevention

2**Description**

Control group: In the control group, 45 minutes before angiography / angioplasty, inflating the 10 mm Hg pressure gauge cuff is performed less than systolic pressure in the elbow area with standard treatment. If creatinine increases more than 0.5 mg / dL or eGFR decreases, more than 25% of contrast-enhanced nephropathy is considered.

Category

Prevention

Recruitment centers**1****Recruitment center****Name of recruitment center**

Dr. Shariati hospital

Full name of responsible person

Seyed Shafi Shafipoor

Street address

Dr. Shariati hospital, North Karegar Ave, Jalal-e-Al-e-Ahmad Hwy

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Email

milad.shafipoor@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraian

Street address

No. 6 floor, Central Organization of the University, Corner of Quds Street, Keshavarz Ave.

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Fax**Email**

vcr@tums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

Seyed Shafi Shafipoor

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Cardiology

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

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Position

Associate professor

Latest degree

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Other areas of specialty/work
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Person responsible for updating data

Contact
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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

Yes - There is a plan to make this available

Title and more details about the data/document

All data can be shared after people have not been identified.

When the data will become available and for how long

Immediately after the publication of the results.

To whom data/document is available

Researchers working in academic and scientific institutions.

Under which criteria data/document could be used

Any analysis is allowed.

From where data/document is obtainable

seyed shafi shafipoor milad.shafipoor@gmail.com

What processes are involved for a request to access data/document

If the article is published, the data will be given as soon as possible after the request.

Comments