

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of Effectiveness of Remote Ischemic Preconditioning effects(RIPC) on Contrast Induced Nephropathy in patients undergoing Coronary Angiography and Angioplasty

Protocol summary

Study aim

Effectiveness of Remote Ischemic Preconditioning in Contrast Induced Nephropathy in high risk patients

Design

100 high risk patients for contrast induced nephropathy randomized in 2 parallel groups for RIPC

Settings and conduct

Elective stable ischemic heart disease with chronic kidney disease candidate for coronary angiography and angioplasty in Rajaie Heart center undergone RIPC, with protocol of 4 time cuff inflation in 5 minute about 50 mmhg upper systolic blood pressure and deflate for 5 min and 10 mmhg upper than diastolic blood pressure in control group

Participants/Inclusion and exclusion criteria

patients within 18-80 years old Satisfaction for this study elective stable ischemic heart disease without need for urgent angiography high risk patients for CIN

Intervention groups

100 high risk patients for contrast induced nephropathy undergoing coronary angiography or angioplasty randomized in 2 groups with RIPC in on group and no intervention in control group

Main outcome variables

Contrast Induced Nephropathy

General information

Reason for update

Acronym

RIPC

IRCT registration information

IRCT registration number: **IRCT20171230038144N1**

Registration date: **2018-05-20, 1397/02/30**

Registration timing: **retrospective**

Last update: **2018-05-20, 1397/02/30**

Update count: **0**

Registration date

2018-05-20, 1397/02/30

Registrant information

Name

Hoda Raffiei jeoldar

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 2392 2078

Email address

h.b.raffiei@rhc.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-23, 1396/10/02

Expected recruitment end date

2018-02-21, 1396/12/02

Actual recruitment start date

2017-12-23, 1396/10/02

Actual recruitment end date

2018-02-21, 1396/12/02

Trial completion date

empty

Scientific title

Comparison of Effectiveness of Remote Ischemic Preconditioning effects(RIPC) on Contrast Induced Nephropathy in patients undergoing Coronary Angiography and Angioplasty

Public title

Comparison of Effectiveness of Remote Ischemic Preconditioning effects(RIPC) on Contrast Induced Nephropathy in patients undergoing Coronary

Angiography and Angioplasty

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

patients with stable ischemic heart disease candidate for coronary angiography or angioplasty chronic kidney disease patients within 18-80 years old

Exclusion criteria:

patients unsatisfaction

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **100**

Actual sample size reached: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Balanced block random with Random Allow,version:1.2 software

Blinding (investigator's opinion)

Double blinded

Blinding description

Pateints with serum creatinine more than 1.4 mg/dl or glumerolar filtration rate less than 60 divided in 2 random groups with Balanced block random with Random Allow,version:1.2 software

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iran University of Medical Scinses

Street address

Iran University of Medical Scinsce, Hemat highway ,
Next to Milad Tower, Tehran ,Iran

City

Tehran

Province

Tehran

Postal code

۱۳۴۹۶۱۴۵۳۵

Approval date

2017-12-23, 1396/10/02

Ethics committee reference number

IR.IUMS.FMD.REC 1396.9311171014

Health conditions studied

1

Description of health condition studied

Contrast Induced Nephropathy

ICD-10 code

N14.1

ICD-10 code description

Nephropathy induced by other drugs, medicaments and biological substances

Primary outcomes

1

Description

Creatinine level and Glomerular filtration rate and urinary output before coronaary angiography and angioplasty and in 3-5 days after procedure

Timepoint

before coronary angiography and angioplasty and in 3-5 days after procedure

Method of measurement

Increase 0.5mg/dl or 25% in serum creatinine levele

Secondary outcomes

empty

Intervention groups

1

Description

Elective stable ischemic heart disease with chronic kidney disease candidate for coronary angiography and angioplasty in Rajaie Heart cneter undergone RIPC,in intervention group we have with protocol of 4 time cuff inflation in 5 minute about 50 mmhg upper systolic blood pressure and deflate for 5 minute.

Category

Treatment - Devices

2

Description

Control group:In control placebo group10 mmhg upper than diastolic blood pressure in 4 time inflation and deflation in 5 minute and creatinine level and urinary output evaluate in 2-7 days after angiography

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rajaei Heart Center

Full name of responsible person

Hoda Raffiei Jelodar

Street address

Rajae Cardiovascular, Medical and Research Center
Vali Asr Ave, Nyayesh Cross Tehran, Iran

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Seyed Kazem Malakoti

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Email

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Web page address

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Hoda Raffiei jelodar

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Cardiology

Street address

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Person responsible for scientific inquiries

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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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Data and analysis file would be available in SPSS format

When the data will become available and for how long

From 1397

To whom data/document is available

Physicians

Under which criteria data/document could be used

Clinical and medical management

From where data/document is obtainable

hoda raffiei jelodar

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

One week after received email data will send

Comments

Tell me about why they need our data