Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of cardiac remote ischemic preconditioning (IRPC) on the release of cardiac troponin I after elective percutaneous coronary intervention (PCI) in outpatients admitted to the angiography ward

Protocol summary

Study aim
Evaluation of the effect of cardiac ischemic preconditioning on the release of cardiac troponin I after elective percutaneous coronary intervention

Design
Single-blinded randomized controlled clinical trial, randomization by random allocation software, sample size of 240 patients (120 in each group), interventionist blinded to groups

Settings and conduct
Patients with CAD who are referred to Bandar Abbas Shahid Mohammadi Hospital by the attendings for elective PCI as outpatients, an hour before PCI undergo intervention (or no intervention) according to their grouping. Then PCI is performed on all patients by an interventionist blinded to the grouping and the PCI method is chosen by him according to the patients' conditions. Biochemical tests are also performed without knowledge of the grouping.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1. Age of 18 years or older 2. Stable coronary artery disease 3. Requirement of elective PCI (percutaneous coronary intervention) Exclusion criteria: 1. Emergency PCI 2. Renal dysfunction 3. High level of cardiac troponin before PCI 4. Women of childbearing age 5. Use of Nicorandil or Glibenclamide 6. Severe comorbidities (terminal illnesses, advanced cancers with low life expectancy, renal and hepatic failure, rheumatic diseases)

Intervention groups
An hour before PCI, in the RIPC group a pressure cuff is inflated on the non-dominant arm to 200 mm/Hg for 5 minutes and then it is deflated after 5 minutes. This cycle is repeated 2 more times. Patients in the control group have a deflated cuff placed on their non-dominant arm for 30 minutes and no inflation-deflation is performed.

Main outcome variables
CKMB; Troponin I, GFR

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180306038978N1**
Registration date: **2019-05-28, 1398/03/07**
Registration timing: **retrospective**

Last update: **2019-05-28, 1398/03/07**
Update count: **0**

Registration date
2019-05-28, 1398/03/07

Registrant information

Name
Shoeib Paskhandi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 76 3331 0012

Email address
shoeibpaskhandi@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-10-06, 1397/07/14

Expected recruitment end date
2018-12-21, 1397/09/30

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of cardiac remote ischemic preconditioning (IRPC) on the release of cardiac troponin I after elective percutaneous coronary intervention (PCI) in outpatients admitted to the angiography ward

Public title

The effect of cardiac remote ischemic preconditioning (IRPC) on the release of cardiac troponin I after elective percutaneous coronary intervention (PCI)

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 18 years or older Stable coronary artery disease Requirement of elective PCI

Exclusion criteria:

Emergency PCI Renal dysfucntion High cardiac troponin levels before PCI Women of childbearing age Use of Nicorandil or Glibenclamide Severe comorbidities (terminal illnesses, advanced cancers with low life expectancy, renal failure, hepatic failure, rheumatic diseases)

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **240**

Randomization (investigator's opinion)

Randomized

Randomization description

Subjects were randomized into two groups by means of a randomization table acquired from the Random Allocation software. for example: 0001: Control 0041: Case 0081: Case 0121: Case 0161: Control 0201: Case

Blinding (investigator's opinion)

Not blinded

Blinding description

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

Jomhouri Eslami Blvd, Shahid Mohammadi Hospital, Bandar Abbas

City

Bandar Abbas

Province

Hormozgan

Postal code

7919915519

Approval date

2018-03-06, 1396/12/15

Ethics committee reference number

HUMS.REC.1396.93

Health conditions studied

1

Description of health condition studied

Ischemic heart disease

ICD-10 code

I24.9

ICD-10 code description

Acute ischemic heart disease, unspecified

Primary outcomes

1

Description

Cardiac troponin I

Timepoint

Cardiac troponin I is measured right before and 18 hours after percutaneous coronary intervention

Method of measurement

Quantitative measurement of cardiac troponin I using enzymatic method

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: An hour before percutaneous coronary intervention a blood pressure cuff will be placed around the non-dominant arm of the patients, then it will be inflated up to 200 mmHg for 5 minutes, afterwards the cuff will be deflated for 5 minutes and this cycle will be repeated two more times.

Category

Prevention

2

Description

Control group: An hour before percutaneous coronary intervention deflated blood pressure cuff will be placed on the non-dominant arm of the patients for 30 minutes.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Catheterization laboratory of Shahid Mohammadi Hospital

Full name of responsible person

Shoeib Paskhandi

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Shahid Mohammadi Hospital, Jomhouri Eslami Blvd, Bandar Abbas

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bandare-abbas University of Medical Sciences

Full name of responsible person

Hossein Farshidi

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Bandar Abbas Faculty of Medicine, Imam Hossein Blvd., Hormozgan, Iran

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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

Shoeib Paskhandi

Position

Resident

Latest degree

Specialist

Other areas of specialty/work

Cardiology

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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
Primary outcome and demographic data
When the data will become available and for how long
Starting 1 year after publication of the results
To whom data/document is available
Researchers working in academic institutions
Under which criteria data/document could be used
Only analyses not indicated in the published article are allowed.
From where data/document is obtainable
Applicants can use the following email address to submit their requests and an SPSS data file will be available to them. shoeibpaskhandi@yahoo.com
What processes are involved for a request to access data/document
Valid identification card indicating that the applicant is a member of academic institutions
Comments