

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

A study on effects of ischemic preconditioning on the occurrence rate of major cardiovascular complications in patients suffering from acute myocardial infarction with ST segment elevation

Protocol summary

Study aim

Determining the effect of Remote Ischemic Preconditioning(RIC) on the incidence of cardiovascular major complications in patients with acute myocardial infarction with ST-segment elevation(STEMI)

Design

Study of single-blind randomized clinical trial with STEMI patients and Primary percutaneous coronary intervention candidates in both intervention and control groups 80 patients in the intervention group and 80 patients in the control group based on consecutive sampling and having inclusion criteria based on four random blocks whose sequence by Sealed Envelope software block randomization specified, will be reviewed.

Settings and conduct

Patients who are referred to the emergency department of Heshmat Hospital due to STEMI. Patients in the intervention group, before PCI, undergo Ischemic Preconditioning Remote in such a way that their upper limbs are subjected to ischemia 3 times with a pressure cuff of 30 mmHg above systolic pressure and each time for 5 minutes They are stretched and then emptied for 5 minutes. However, in the control group, only the pressure gauge cuff is closed. Finally, the information obtained is recorded in a checklist.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients over 18 years of age with chest pain and onset of pain less than 12 hours and ECG with ST-elevation equal or higher than 0.1mv in two leads together Exclusion criteria: cardiogenic shock. dying before or immediately after . past myocardial infarction or vascular bypass surgery. 12 hours or more have elapsed since the onset of maximal chest pain.

Intervention groups

Patients referred due to STEMI are included in the study and the RIC procedure is performed on patients in the case group.

Main outcome variables

LVEF; stroke; Myocardial reinfarction; New heart failure; Death

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200510047380N2**

Registration date: **2022-01-29, 1400/11/09**

Registration timing: **registered_while_recruiting**

Last update: **2022-01-29, 1400/11/09**

Update count: **0**

Registration date

2022-01-29, 1400/11/09

Registrant information

Name

Aboozar Fakhri Mousavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3366 4282

Email address

aboozar.mousavi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-22, 1400/10/01

Expected recruitment end date

2022-08-23, 1401/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A study on effects of ischemic preconditioning on the occurrence rate of major cardiovascular complications in patients suffering from acute myocardial infarction with ST segment elevation

Public title

The effect of ischemic preconditioning in patients with acute Myocardial infarction

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients over 18 coming into the emergency room because of chest pain that has started less than 12 hours before ECG shows ST elevation equaling or higher than 0.1 millivolt in two parallel leads (ST elevation equals or is higher than 0.2 millivolt in V1 to V3 leads)

Exclusion criteria:

Patients in cardiogenic shock Patients who die before or immediately after percutaneous coronary intervention (PCI) Patients with a history of myocardial infarction or coronary artery bypass graft 12 hours or more have elapsed since the onset of maximal chest pain

Age

From 18 years old

Gender

Both

Phase

N/A

Groups that have been masked

- Care provider
- Investigator

Sample size

Target sample size: 160

Randomization (investigator's opinion)

Randomized

Randomization description

According to the estimated sample size, 80 patients in the intervention group and 80 patients in the control group based on consecutive sampling and having inclusion criteria based on four random blocks whose sequence by Sealed Envelope software Ltd. 2021. Created a block Randomisation list {Online} Available from: <https://www.sealedenvelope.com/simple-randomiser/v1/lists> {Accessed 13 Sep 2021} The list is kept inside a sealed letter at the Healthy Heart Research Center. After permission to conduct the study, patients are assigned to the intervention and control groups on a daily basis. It should be noted that this sequence list consists of 40 quadruple random blocks. This study is a single-blind clinical trial study. The method of blinding in the study will be that the intervention of patients by one of the assistants and the evaluation of complications and measurement of left ventricular ejection fraction by

another assistant. Patients have no information about the type of intervention.

Blinding (investigator's opinion)

Single blinded

Blinding description

This study is a single-blind clinical trial. The independent variable in this study is the intervention group against control group, the outcomes of this study (heart failure, recurring myocardial infarction, stroke and death) are the primary end points, and ejection fraction (EF) is the secondary end point.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary IDs**

empty

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

Research Ethics Committees of Guilan university of medical sciences

Street address

Dr Heshmat Hospital, Mosalla Square, Rasht, Guilan

City

Rasht

Province

Guilan

Postal code

4193955588

Approval date

2021-09-29, 1400/07/07

Ethics committee reference number

IR.GUMS.REC.1400.308

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

ST segment elevation acute myocardial infarction

ICD-10 code

I24.9

ICD-10 code description

Acute ischemic heart disease, unspecified

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

Patients with acute ST-segment elevation myocardial infarction

Timepoint

Before the intervention and 3 months later and 6 months

after acute myocardial infarction
Method of measurement
Based on electrocardiogram tape

+98 13 3366 3070
Email
aboozar-fm@yahoo.com

Secondary outcomes

1

Description

Heart failure, recurrent myocardial infarction, stroke and death, left ventricular ejection fraction

Timepoint

Before the intervention, 3 months later and 6 months later

Method of measurement

Through a researcher-made questionnaire and echocardiography device

Intervention groups

1

Description

Patients with acute myocardial infarction with ST-segment elevation who are candidates for Primary PCI and undergo RIC. The cuff is placed on one of the upper limbs and inflated to 30 mm/hg higher than systolic pressure for a period of 5 minutes. The process is repeated 3 times with a 5-minute interval.

Category

Rehabilitation

2

Description

Control group: Patients with acute myocardial infarction with ST-segment elevation who were candidates for Primary PCI. The cuff is placed on one of the upper limbs and inflated to 30 mm/hg higher than systolic pressure for a period of 5 minutes. The process is repeated 3 times with a 5-minute interval.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Heshmat Hospital

Full name of responsible person

Seyyed Aboozar Fakhr Mousavi

Street address

Dr Heshmat Hospital, Mosalla square, Rasht, Guilan

City

Rasht

Province

Guilan

Postal code

4193955588

Phone

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rasht University of Medical Sciences

Full name of responsible person

Dr Mohammadreza Naghi Pour

Street address

Dr Heshmat Hospital, Mosalla square, Rasht, Guilan

City

Rasht

Province

Guilan

Postal code

4193955588

Phone

+98 13 3366 3070

Email

aboozar-fm@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Rasht 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

Rasht University of Medical Sciences

Full name of responsible person

Seyyed Aboozar Fakhr Mousavi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Cardiology

Street address

Dr Heshmat Hospital, Mosalla square

City

Rasht

Province

Guilan
Postal code
4193955588
Phone
+98 13 3366 3070
Email
aboozar-fm@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Seyyed Aboozar Fakhr Mousavi
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Cardiology
Street address
Dr Heshmat Hospital, Mosalla square
City
Rasht
Province
Guilan
Postal code
4193955588
Phone
+98 13 3366 3070
Email
aboozar-fm@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Seyyed Aboozar Fakhr Mousavi
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Cardiology
Street address
Dr Heshmat Hospital, Mosalla square
City
Rasht

Province
Guilan
Postal code
4193955588
Phone
+98 13 3366 3070
Email
aboozar-fm@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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

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

Title and more details about the data/document

All data is potentially shareable after unidentified individuals.

When the data will become available and for how long

Access period 6 months after printing the results

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

In order to conduct further research at the written request of the Scientific Institute.

From where data/document is obtainable

applicants for receiving documents and data can refer to the Healthy Heart Research Center located in Heshmat Hospital. They can also call 01333664282.

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

The applicant can refer to the Healthy Heart Research Center after receiving Confirmation from the project manager, the documents and data will be available to him within a week.

Comments