

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

A clinical trial to compare the effectiveness of remote ischemic preconditioning and primary coronary percutaneous intervention on cardiovascular outcomes in patients with acute myocardial infarction

Protocol summary

Study aim

A clinical trial to compare the effectiveness of remote ischemic preconditioning and primary coronary percutaneous intervention on cardiovascular outcomes in patients with acute myocardial infarction.

Design

In this pragmatic double-blind, controlled clinical trial, sixty patients with acute myocardial infarction were assigned into parallel groups using the table of random numbers in a community-based setting.

Settings and conduct

Patients with acute myocardial infarction at the Department of Cardiology, Ghaem Hospital, Mashhad, Iran, were chosen. In this double-blind study, the clinical care and data collector were blind to group assignment and the type of treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age higher than 20 years; an elapse of 12 hours from the primary diagnosis. Exclusion criteria: Thrombolysis in myocardial infarction (TIMI) score of 2-3; Rentrop grade of >1; need for coronary artery bypass graft; cardiogenic shock.

Intervention groups

The intervention group will receive remote ischemic preconditioning. In this method, a blood pressure cuff is fastened on one of the patient's organs before surgery, and the cuff is intermittently blown and drained to restrict blood flow and reestablish it. The control group will receive primary coronary percutaneous intervention. In this method, a tube with a balloon at the end, called the catheter, is moved into the coronary artery toward the blockage. After the dilatation of the vessel, the balloon is evacuated, and the catheter is pulled out.

Main outcome variables

Evaluation and comparison of major adverse cardiovascular events (mortality, second myocardial infarction, etc), the reduction of ST-segment as an

indicator of microvascular reperfusion, thrombolysis in myocardial infarction flow, and cardiac enzymes before and 24 hours after the intervention in the intervention and control groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150614022713N2**

Registration date: **2018-11-29, 1397/09/08**

Registration timing: **prospective**

Last update: **2018-11-29, 1397/09/08**

Update count: **0**

Registration date

2018-11-29, 1397/09/08

Registrant information

Name

Masoud Sajadi

Name of organization / entity

Imam Reza Hospital

Country

Iran (Islamic Republic of)

Phone

+98 51 3840 0000

Email address

sajjadim961@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-22, 1397/10/01

Expected recruitment end date

2020-01-21, 1398/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial to compare the effectiveness of remote ischemic preconditioning and primary coronary percutaneous intervention on cardiovascular outcomes in patients with acute myocardial infarction

Public title

The effect of remote ischemic preconditioning in patients with acute myocardial infarction

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age higher than 20 years An elapse of 12 hours form the primary diagnosis

Exclusion criteria:

Thrombolysis in myocardial infarction (TIMI) score of 2-3
Rentrop grade of >1 Need for coronary artery bypass graft Cardiogenic shock

AgeFrom **20 years** old**Gender**

Both

Phase

2-3

Groups that have been masked

- Care provider
- Outcome assessor

Sample sizeTarget sample size: **60****Randomization (investigator's opinion)**

Randomized

Randomization description

Sixty patients with acute myocardial infarction at the Department of Cardiology in Ghaem Hospital, Mashhad, Iran, were chosen. The participants were allocated into two groups of intervention and control using the table of random numbers based on computer programs.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients with acute myocardial infarction at the Department of Cardiology, Ghaem Hospital, Mashhad, Iran, were chosen. In this double-blind study, the clinical care and data collector were blind to group assignment and the type of treatment.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Vice Chancellor for Research, Mashhad University of Medical Sciences

Street address

Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street

City

Mashhad

Province

Razavi Khorasan

Postal code

9195965919

Approval date

2018-10-02, 1397/07/10

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1397.340

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

Acute myocardial infarction

ICD-10 code

I21

ICD-10 code description

Acute myocardial infarction

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

Major adverse cardiovascular events (i.e., mortality, second myocardial infarction, and stroke during admission)

Timepoint

Before and 24 hours after the intervention

Method of measurement

Echocardiography

2**Description**

The reduction of ST-segment as an indicator of microvascular reperfusion

Timepoint

Before and 24 hours after the intervention

Method of measurement

Electrocardiogram (ECG)

3

Description

Thrombolysis in myocardial infarction flow

Timepoint

Before and 24 hours after the intervention

Method of measurement

Thrombolysis in Myocardial Infarction (TIMI) flow

Secondary outcomes

1

Description

Cardiac enzymes

Timepoint

Before and 24 hours after the intervention

Method of measurement

Blood test

Intervention groups

1

Description

Intervention group: The intervention group will receive remote ischemic preconditioning. In this method, a blood pressure cuff is fastened on one of the patient's organs before surgery, and the cuff is intermittently blown and drained to restrict blood flow and reestablish it.

Category

Treatment - Other

2

Description

Control group: The control group will receive primary coronary percutaneous intervention. In this method, a tube with a balloon at the end, called the catheter, is moved into the coronary artery toward the blockage. After the dilatation of the vessel, the balloon is evacuated, and the catheter is pulled out.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem Hospital

Full name of responsible person

Masoud Sajjadi

Street address

Ghaem Hospital, Ahmadabad Street, Dr. Ali Shariati Square

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91766-99199

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

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Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Masoud Sajjadi

Position

Fellowship

Latest degree

Specialist

Other areas of specialty/work

Cardiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Masoud Sajjadi

Position

Fellowship

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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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

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

Not applicable

Title and more details about the data/document

The total data to be included are the primary and secondary effects to be shared.

When the data will become available and for how long

6 months after printing results

To whom data/document is available

Our data will only be available to researchers working in science center and university.

Under which criteria data/document could be used

Our data will be available for scholars working in science center and university.

From where data/document is obtainable

Masoud Sajjadi provides the analysis code to the applicants via email: sajjadim961@mums.ac.ir

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

Data collection was done for 10 months, data were collected one month, statistical analysis of one month, information dissemination as a article six months.

Comments