

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

Effect of normal saline intra-coronary injection versus no injection on the complications of re-perfusion during primary angioplasty in patients with acute myocardial infarction: a randomized clinical trial

Protocol summary

Study aim

To assess the effect of normal saline intracoronary injection versus no injection on the complications of reperfusion during primary angioplasty in patients with acute myocardial infarction

Design

This is a randomized clinical trial, in which 30 eligible patients will be randomly assigned to the intervention and control groups

Settings and conduct

The eligible patients with acute myocardial infarction who will refer to Farshchian Heart Hospital in Hamadan city during the study period will be enrolled in the trial and will be randomly assigned to the intervention and control groups through the drawing of lots.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 75 years, Acute myocardial infarction, ST-elevation
Exclusion criteria: Need for cardiac surgery

Intervention groups

Intervention group: Routine angioplasty plus an injection of normal saline at 22 ° C at a speed of 20 ml/min into the coronary artery for 10 minutes
Control group: Routine angioplasty

Main outcome variables

Primary outcome: Heart perfusion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120215009014N316**
Registration date: **2019-11-14, 1398/08/23**
Registration timing: **registered_while_recruiting**

Last update: **2019-11-14, 1398/08/23**

Update count: **0**

Registration date

2019-11-14, 1398/08/23

Registrant information

Name

Jalal Poorolajal

Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan
University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 81 1838 0090

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-21, 1397/11/01

Expected recruitment end date

2020-07-21, 1399/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of normal saline intra-coronary injection versus no injection on the complications of re-perfusion during primary angioplasty in patients with acute myocardial infarction: a randomized clinical trial

Public title

Effect of normal saline intra-coronary injection versus no

injection on the complications of re-perfusion during primary angioplasty in patients with acute myocardial infarction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 18 to 75 years, Acute myocardial infarction, ST-elevation

Exclusion criteria:

Need to cardiac surgery

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment of the patients to the intervention and control groups through the drawing of lots. To do this, we prepare two sheets and write "intervention" on one sheet and "control" on another. Then, by referring each patient, one of the sheets will be randomly taken and the patient will be assigned to the intervention or control group.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Vice-chancellor for Research and Technology,
Hamadan University of Medical Sciences, Shahid
Fahmideh Ave

City

Hamadan

Province

Hamadan

Postal code

6517838695

Approval date

2018-10-13, 1397/07/21

Ethics committee reference number

IR.UMSHA.REC.1397.478

Health conditions studied

1

Description of health condition studied

Myocardial infarction

ICD-10 code

I22.9

ICD-10 code description

Subsequent ST elevation (STEMI) myocardial infarction of unspecified site

Primary outcomes

1

Description

Heart perfusion

Timepoint

Before the intervention and 30 days after that

Method of measurement

By echocardiography

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Routine angioplasty plus an injection of normal saline at 22 ° C at a speed of 20 ml/min into the coronary artery for 10 minutes

Category

Treatment - Drugs

2

Description

Control group: Routine angioplasty without an injection of normal saline

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Farshchian Heart Hospital in Hamadan city

Full name of responsible person

Dr Mahshid Mokhayari

Street address

Farshchian Heart Hospital, Shahid Fahmideh Ave.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
Hamedan 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
Hamedan University of Medical Sciences
Full name of responsible person
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Position
Resident of Cardiology
Latest degree

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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