

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Effect of primary angioplasty with and without remote ischemic postconditioning in a patient's hand on the level of oxidative stress in patients with acute myocardial infarction

Protocol summary

Summary

The study included 82 patients with a first acute myocardial infarction who have come to the emergency department and are candidate for primary angioplasty. Patients are allocated into two groups (intervention and control group) based on the Randomization.org. Patients with 20- 80 years old and with first myocardial infarction who have come in the first 12 hours after onset of symptoms, in the absence of contraindication of thrombolytic therapy are candidates to be studied. Patients with left bundle branch block, pacemakers, cardiogenic shock, are excluded. In both groups three cycles of inflation and deflation of cuff, each one for 5 minutes, will be intermittent implemented. According this protocol, in the study group the cuff will be inflated to 30 mmHg upper than systolic pressure for 5 min and then for 5 min deflation. In the control group pressure inflation will be done to 30 mmHg lower than diastolic pressure. Blood samples for assessment of oxidative stress factors, 10 min and 1 hour after the start of the protocol was prepared and Extracted serum from that samples stored at -70 freezer. To evaluate the level of oxidative stress, SOD, GPX, and TAC will be measured. Oxidative stress level compared the two groups together. The purpose of this study is using this protocol as a post-conditioning factor during primary angioplasty in acute myocardial infarction patients to reduce or avoid increasing the size of the infarct.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014101416229N4**

Registration date: **2015-05-10, 1394/02/20**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-05-10, 1394/02/20

Registrant information

Name

Samad Ghaffari

Name of organization / entity

Cardiovascular Research Center, Tabriz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

Expected recruitment start date

2014-11-01, 1393/08/10

Expected recruitment end date

2015-05-01, 1394/02/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of primary angioplasty with and without remote ischemic postconditioning in a patient's hand on the level of oxidative stress in patients with acute myocardial infarction

Public title

Remote ischemic postconditioning in Acute myocardial infarction

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: 1) Age between 20-80 years 2) Patients with a first MI in the first 12 hours after symptoms have gone. 3) Patients who have not received thrombolysis 4) Don't having severe disease 5) Not having the use of drugs cytotoxic and radiation 6) No blood transfusion in the last month 7) Willingness to participate in the study 8) patients with BMI = 26 ± 5 Exclusion criteria: 1) Receiving other treatment, such as the thrombolytic therapy or emergency bypass 2) Patients with LBBB 3) People who have heart pacemakers 4) Patients with cardiogenic shock 5) Patients who received DC shock

Age

From **20 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **82**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

All patients in the study, will be unaware of patients' access to grouping. The person responsible for data analysis and laboratory analyzers will be unaware of patients' access to grouping.

Secondary Ids

empty

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

Ethics committee of Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences- university street

City

Tabriz

Postal code**Approval date**

2014-10-09, 1393/07/17

Ethics committee reference number

93110

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

Acute myocardial infarction

ICD-10 code

I21.0, I21

ICD-10 code description

Acute transmural myocardial infarction of anterior wall,
Acute transmural myocardial infarction of inferior wall,
Acute transmural myocardial infarction of other sites

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

Oxidative Stress

Timepoint

Blood samples were collected at the opening of the vessel and then 60 minutes after the start of the procedure

Method of measurement

Spectrophotometry using specific kits

Secondary outcomes**1****Description**

ST Resolution

Timepoint

Electrocardiography before intervention and 90 minute after then

Method of measurement

Electrocardiography

Intervention groups**1****Description**

In the control group, the cuff pumped for 5 minutes to 30 mmHg under diastolic pressure of patient and then opens for 5 minutes. This procedure is performed three times for 5 minutes.

Category

Prevention

2**Description**

In the test group cuff pumped for 5 minutes to 30 mmHg above systolic pressure of patient and then opens for 5 minutes. This procedure is performed three times for 5 minutes.

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Madani Hospital
Full name of responsible person
Hassan Ali Lotfollahi
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Cat. Lab - Shahid Madani Hospital
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Cardiovascular Research Center of Tabriz University of Medical Sciences
Full name of responsible person
Samad Ghafari
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university st. Imam Avenue
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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
Cardiovascular Research Center of Tabriz University of Medical Sciences
Proportion provided by this source
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

2

Sponsor

Name of organization / entity
Vice chancellor for research, Tabriz University of Medical Sciences
Full name of responsible person
Mohammad Reza Rashidi
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Vice chancellor for research- Tabriz University of Medical Sciences
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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
Vice chancellor for research, Tabriz University of Medical Sciences
Proportion provided by this source
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty