

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 2026

### A clinical trial on the effectiveness of intracoronary adenosine for the prevention of no-reflow phenomenon in patients with acute myocardial infarction

#### Protocol summary

##### Study aim

A clinical trial on the effectiveness of intracoronary adenosine for the prevention of no-reflow phenomenon in patients with acute myocardial infarction

##### Design

In this pragmatic double-blind, controlled clinical trial, 126 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 older than 20 years; an elapse of 12 hours from the primary diagnosis. Exclusion criteria: suffering chronic obstructive pulmonary disease, asthma, less than 90 mm Hg systolic blood pressure, cardiac arrhythmia, sick sinus syndrome and neuropathy; candidates for coronary artery bypass grafts; using other medicines, such as verapamil.

##### Intervention groups

The control group will receive 3 mcg adenosine in 50 cc normal saline. The low dose intervention group will receive 120 mcg adenosine for involvement of right coronary artery and 240 mcg adenosine for involvement of left coronary artery. The high dose intervention group will receive 240 mcg adenosine for involvement of right coronary artery and 480 mcg adenosine for involvement of left coronary artery.

##### Main outcome variables

Evaluation and comparison of major adverse cardiovascular events (i.e., mortality, second myocardial infarction, and stroke during admission), ejection fraction of ventricular, the reduction of ST-segment and

thrombolysis in myocardial infarction flow 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: **IRCT20190112042329N1**

Registration date: **2019-03-03, 1397/12/12**

Registration timing: **prospective**

Last update: **2019-03-03, 1397/12/12**

Update count: **0**

##### Registration date

2019-03-03, 1397/12/12

##### Registrant information

##### Name

Mustafa Baburian

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3801 2739

##### Email address

babourianm941@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-03-21, 1398/01/01

##### Expected recruitment end date

2020-04-20, 1399/02/01

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

A clinical trial on the effectiveness of intracoronary adenosine for the prevention of no-reflow phenomenon in patients with acute myocardial infarction

**Public title**

Effect of intracoronary adenosine 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:**

Having chronic obstructive pulmonary disease, asthma, less than 90 mm Hg systolic blood pressure, cardiac arrhythmia, sick sinus syndrome and neuropathy  
Candidates for coronary artery bypass grafts Using other medicines, such as verapamil

**Age**

From **20 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

- Care provider
- Outcome assessor

**Sample size**

Target sample size: **126**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Totally 126 patients with acute myocardial infarction at the Department of Cardiology in Ghaem Hospital, Mashhad, Iran, were chosen. The participants were allocated into 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**

Ethics Committee of 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**

2018-10-16, 1397/07/24

**Ethics committee reference number**

IR.MUMS.MEDICAL.REC.1397.678

**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**

Ejection fraction of ventricular

**Timepoint**

Before and 24 hours after the intervention

**Method of measurement**

Echocardiography

## Secondary outcomes

### 1

#### Description

The reduction of ST-segment

#### Timepoint

Before and 24 hours after the intervention

#### Method of measurement

Electrocardiogram (ECG)

### 2

#### Description

Thrombolysis in myocardial infarction flow

#### Timepoint

Before and 24 hours after the intervention

#### Method of measurement

TIMI flow grading

## Intervention groups

### 1

#### Description

Control group: the control group will receive 3 mcg adenosine in 50 cc normal saline.

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group: the low dose intervention group will receive 120 mcg adenosine for involvement of right coronary artery and 240 mcg adenosine for involvement of left coronary artery.

#### Category

Treatment - Drugs

### 3

#### Description

Intervention group: the high dose intervention group will receive 240 mcg adenosine for involvement of right coronary artery and 480 mcg adenosine for involvement of left coronary artery.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Ghaem Hospital

##### Full name of responsible person

Mustafa Baburian

##### Street address

Ghaem Hospital, Ahmadabad Street, Dr. Ali Shariati Square

#### City

Mashhad

#### Province

Razavi Khorasan

#### Postal code

9176699199

#### Phone

+98 51 3840 0000

#### Email

babourianm941@mums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Full name of responsible person

Mohsen Tafaghodi

##### Street address

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

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

913753459

##### Phone

+98 51 3841 1538

##### Email

vcresearch@mums.ac.ir

#### 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

Mustafa Baburian

##### Position

Residents

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Cardiology

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Ghaem Hospital, Ahmadabad Street, Dr. Ali Shariati Square

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Mustafa Baburian

**Position**

Residents

**Latest degree**

Medical doctor

**Other areas of specialty/work**

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**Email**

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**Person responsible for updating data****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Mustafa Baburian

**Position**

Residents

**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**

Yes - There is a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

Information on the main outcome or the like can 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 at science centers and universities.

**Under which criteria data/document could be used**

Our data will be available for scholars working at science centers and universities

**From where data/document is obtainable**

Mustafa Baburian provides the data analysis to the applicants via email: babourianm941@mums.ac.ir

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

Applicants can respond to the email of the respondent and receive a response within a week.

**Comments**