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 form 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
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

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
Cardiology
Street address
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City
Mashhad
Province
Razavi Khorasan
Postal code
9176699199
Phone
+98 51 3840 0000
Email
babourianm941@mums.ac.ir

Person responsible for updating data

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
Street address
Ghaem Hospital, Ahmadabad Street, Dr. Ali Shariati Square
City
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Province
Razavi Khorasan
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Email
babourianm941@mums.ac.ir

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