

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Effect of prophylactic intracoronary adenosine injection during percutaneous coronary intervention on Thrombolysis In Myocardial Infarction frame count in patients with non ST-elevation myocardial infarction

Protocol summary

Study aim

Evaluation the effect of prophylactic adenosine intracoronary injection in patients with non ST elevation myocardial infarction (NSTEMI) who underwent angioplasty on the incidence of slow or no reflow phenomenon and periprocedural Major adverse cardiac and cerebral events (MACCE)

Design

This is a phase 2, single center, open label, randomized control trial

Settings and conduct

This trial will be performed on patients with NSTMI and candidate for invasive strategy in the first 72 hours of the onset of symptom, the study steps will be as follow:
1. Patients transfer to catheterization laboratory. 2. Selective coronary angiography performs standard approach. 3. The characteristic of infarct related artery will be assessed and if suitable for stenting, the patients enrolled in the trial.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Chest pain or angina equivalent refer to myocardial ischemia 2. Past < 72 hours from symptoms onset 3. ST depression or T wave inversion in ECG or normal ECG 4. The patients candidate for PCI or coronary stenosis suitable for angioplasty 5. Elevated troponin
Exclusion criteria: 1. History of asthma and chronic obstructive pulmonary disease 2. Life expectancy < 6 months 3. Cardiogenic shock (sustain SBP < 90 mmHg) 4. Post coronary artery bypass surgery 5. Target vessel revascularization 6. Left main lesion or severe three vessels disease

Intervention groups

intracoronary Adenosine as follow: 90 micrograms for left system in 10 cc or 60 micrograms for right system in 10 cc normal saline 0.9% - intracoronary 10 cc Normal saline 0.9% as a placebo.

Main outcome variables

The last Thrombolysis In Myocardial Infarction (TIMI) frame count

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170619034621N2**

Registration date: **2020-02-01, 1398/11/12**

Registration timing: **registered_while_recruiting**

Last update: **2020-02-01, 1398/11/12**

Update count: **0**

Registration date

2020-02-01, 1398/11/12

Registrant information

Name

Azadeh Mozayani Monfared

Name of organization / entity

Hamadan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 3838 1731

Email address

a.mozayani@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-22, 1398/09/01

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
Effect of prophylactic intracoronary adenosine injection during percutaneous coronary intervention on Thrombolysis In Myocardial Infarction frame count in patients with non ST-elevation myocardial infarction

Public title
Effect of prophylactic intracoronary adenosine injection in non ST-elevation myocardial infarction

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
chest pain or equivalent angina refer to myocardial ischemia past less than 72 hours from onset of symptoms ECG with ST depression or T wave inversion or normal ECG elevated troponin the patients candidate for PCI and their coronary stenosis suitable for stenting age more than 18 years fill out an informed constant form
Exclusion criteria:
History of asthma and chronic obstructive pulmonary disease Treatment with dipyridamole life expectancy less than 6 months Cardiogenic shock (sustain SBP<90 mmHg) Post coronary artery bypass graft surgery Atrioventricular block in first ECG ST elevation myocardial infarction History of renal failure (exception patients underwent hemodialysis) Need for Target vessel revascularization (TVR) The coronary artery stenosis will not be suitable for angioplasty Left main lesion or severe 3 vessels disease

Age
From **18 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
4-way block randomization method will be selected, which was performed with designed software system in cath lab, and after entering the patients file code , the group of patient will be identified.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Rajaiee Heart Center

Street address

Hashemirafsanjani Highway

City

Tehran

Province

Tehran

Postal code

1995614331

Approval date

2020-01-25, 1398/11/05

Ethics committee reference number

IR.RHC.REC.1398.073

Health conditions studied

1

Description of health condition studied

Non ST elevation myocardial infarction

ICD-10 code

I21

ICD-10 code description

ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction

Primary outcomes

1

Description

No/slow flow phenomenon

Timepoint

immediately at the end of the procedure

Method of measurement

TIMI frame count in angiography

Secondary outcomes

1

Description

in hospital major adverse cardiac and cerebral events

Timepoint

during hospitalization

Method of measurement

monitoring

2

Description

period of hospitalization

Timepoint

during hospitalization

Method of measurement

measuring the number of day that patient which hospitalized

3

Description

lethal arrhythmia

Timepoint

during hospitalization

Method of measurement

cardiac monitoring

Intervention groups

1

Description

intervention group: Adenosine will be used as the vasodilator drug in this group. It will be prescribed intracoronary via well engaged guiding catheter. The dose will be mentioned as follow: □ 90 micrograms for left system in 10 cc normal saline 0.9% □ 60 micrograms for right system in 10 cc normal saline 0.9%

Category

Prevention

2

Description

Control group: 10 cc Normal saline 0.9% will be used intracoronary via guiding catheters

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rajaiee Heart center

Full name of responsible person

Azadeh Mozayanimonfared

Street address

Hashemi Rafsanjani Hwy

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Tehran

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Postal code

19969 11151

Phone

+98 21 23921

Email

a.mozayani@umsha.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rajaiee Heart Center

Full name of responsible person

Dr. Alireza Rashidinejad

Street address

Hashemi Rafsanjani Hwy

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19969 11151

Phone

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Email

alirezarashidinejad@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Rajaiee Heart Center

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

Shahid Rajaiee Heart Center

Full name of responsible person

Azadeh Mozayanimonfared

Position

Shahid Rajaiee Heart Center

Latest degree

Specialist

Other areas of specialty/work

Cardiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Rajaiee Heart Center

Full name of responsible person

Azadeh Mozayanimonfared

Position

Resident of interventional cardiology

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Latest degree

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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

Yes - There is 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

all collected deidentified IPD

When the data will become available and for how long

immediately after result publication

To whom data/document is available

all researcher

Under which criteria data/document could be used

no limitation

From where data/document is obtainable

a.mozayani@umsha .ac.ir

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

after assessment in research committee during 1 month

Comments