

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Study of the effect of oral nicorandil on ST-segment resolution in patients with acute ST-segment myocardial infarction undergoing primary coronary angioplasty

Protocol summary

Study aim

Effect of oral Nicorandil on ST Resolution in patients with STEMI undergoing primary percutaneous coronary angioplasty

Design

Two arm parallel group randomised trial with blinded postoperative care and outcome assessment

Settings and conduct

Setting: Patients with acute ST-segment elevation myocardial infarction who treated with primary angioplasty either balloon or stenting in Madani heart center, Tabriz, Iran will enroll in present study. Due to possible effect of oral nicorandil in reducing reperfusion injury, intervention group will receive two stat dose of oral nicorandil in emergency room and just before angioplasty in catheterization laboratory. Control group will not receive oral nicorandil. Prevalence of ST-segment resolution more than 50% in electrocardiography between baseline ECG and 60 minutes post angioplasty, will compare between intervention group and control group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with acute STEMI treated with primary angioplasty who admitted within 12 hours of symptom onset. Exclusion criteria: Patients with uninterpretable ECG, LBBB, severe valvular disease, unsuitable coronary anatomy.

Intervention groups

Intervention group will receive two dose of 20 mg nicorandil in emergency department and in catheterization laboratory just before primary angioplasty. Control group will receive only primary angioplasty and usual care.

Main outcome variables

ST-segment resolution

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20140512017666N1**

Registration date: **2018-03-17, 1396/12/26**

Registration timing: **prospective**

Last update: **2018-03-17, 1396/12/26**

Update count: **0**

Registration date

2018-03-17, 1396/12/26

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 1336 3880

Email address

separham@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-20, 1396/12/29

Expected recruitment end date

2018-08-22, 1397/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the effect of oral nicorandil on ST-segment resolution in patients with acute ST-segment myocardial infarction undergoing primary coronary angioplasty

Public title

Oral nicorandil in PPCI

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

patients with first acute STEMI treated with primary angioplasty STEMI definition: Anginal chest pain more than 20 minutes, admission within 12 hours of symptoms onset, ECG ST-segment elevation with at least 2 contiguous ECG leads, >2 fold increase in cardiac enzymes.

Exclusion criteria:

previous history of ischemic heart disease left bundle branch block, paced rhythm, uninterpretable electrocardiogram, severe valvular disease, cardiomyopathy coronary anatomy unsuitable for angioplasty including those requiring coronary bypass surgery or those candidate for medical treatment

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **240**

Randomization (investigator's opinion)

Randomized

Randomization description

block

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 Tabriz university of medical science

Street address

Golgasht street-research deputy

City

Tabriz

Province

East Azarbaijan

Postal code

5165665935

Approval date

2018-02-28, 1396/12/09

Ethics committee reference number

IR.TBZMED.REC.1396.788

Health conditions studied

1

Description of health condition studied

Acute ST-segment myocardial infarction

ICD-10 code

I21.0, I21

ICD-10 code description

Acute myocardial infarction

Primary outcomes

1

Description

ST-segment resolution

Timepoint

60 minutes after primary angioplasty

Method of measurement

Electrocardiogram

Secondary outcomes

1

Description

Left ventricular function

Timepoint

The day after primary angioplasty

Method of measurement

Echocardiography

Intervention groups

1

Description

Intervention group: This group receive 20 milligram nicorandil tablet in Emergency room and another 20 milligram nicorandil in catheterization laboratory just before initiation of primary angioplasty. nicorandil tablets are made by Sanofi company. Nicorandil, a nicotinamide ester, leads to relaxation of smooth tonic vascular muscles in both venous and arterial part of vessels via opening of potassium channel. Its major effect is vasodilation of coronary arteries and relief of ischemia.

Category

Treatment - Drugs

2

Description

Control group: this group receives routine primary angioplasty and routine anti-ischemic drugs

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Madani Heart center

Full name of responsible person

Behnaz Akbari

Street address

Tabriz,Daneshgah street,Madani heart center,Cadiology department

City

Tabriz

Province

East Azarbaijan

Postal code

5166614756

Phone

+98 41 3337 3903

Email

akbari.med@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

dr abolghasem jouyban

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Phone

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Email

ajouyban@hotmail.com

Web page address

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Ahmad Separham

Position

Associate professore

Latest degree

Medical doctor

Other areas of specialty/work

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Position

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

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Full name of responsible person

Ahmad separham

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Latest degree

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Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

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

Yes - There is 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

Title and more details about the data/document

Baseline clinical, and demographic, electrocardiographic and survival of patients will be available.

When the data will become available and for how long

Starting 6 months after publication and for one year

To whom data/document is available

only available for clinicians

Under which criteria data/document could be used

documents are available only for academic purpose and any type of analysis could be done.

From where data/document is obtainable

Data will be available in my personal mail(aseparham@gmail.com) and would be sent to any clinician upon request.

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

upon request by mail

Comments