Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Study of the effect of oral nicorandil on ST-segment resolution in patients with acute ST-segment myocardial infarction undegoing 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 than50% 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 cathetrization 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 undegoing 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 by-pass 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
121.0, 121
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
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5166614756
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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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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
Cardiology
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Person responsible for updating data

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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