# 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 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
**City**
Tabriz
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East Azarbaijan
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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
**Street address**
Golgasht street-main builfing-research deputy
**City**
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**Province**
East Azarbaijan
**Postal code**
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**Phone**
+98 41 3335 7310
**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
**Street address**
Daneshgah street-Madani heart center-cardiology department
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## Person responsible for scientific inquiries

**Contact**
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## Person responsible for updating data

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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**