Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Investigation the effect of oral nicorandil on arrhythmia rate in patients undergoing angioplasty

Protocol summary

Study aim
Investigation the effect of oral nicorandil on arrhythmia rate in patients undergoing angioplasty
Design
Phase 2-3 randomized clinical trial with parallel groups which will be conducted on 100 patients with myocardial infarction
Settings and conduct
This study will be conducted with the aim of investigation the effect of nicorandil on arrhythmia rate in 100 patients with myocardial infarction. After inclusion in the study, using block randomization method with blocks of ten, the patients will be assigned into two groups; intervention group receiving 20 mg oral nicorandil twice a day since admission till discharge and control group receiving nicorandil placebo twice a day since admission till discharge. In each group arrhythmia rate will be evaluated by taking electrocardiogram and its evaluation by cardiologist and will be compared together.
Participants/Inclusion and exclusion criteria
Inclusion criterion: having a definite diagnosis of myocardial infarction. Exclusion criteria: cardiogenic shock; previous use of nicorandil; undergoing cardiopulmonary resuscitation
Intervention groups
Intervention group: Receiving 20 mg nicorandil orally twice a day since admission till discharge Control group: Receiving nicorandil placebo twice a day since admission till discharge
Main outcome variables
Arrhythmia

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20181104041555N1**
Registration date: **2018-12-13, 1397/09/22**
Registration timing: **prospective**

Last update: **2018-12-13, 1397/09/22**
Update count: **0**
Registration date
2018-12-13, 1397/09/22

Registrant information
Name
Hesam Mullazehi
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-12-22, 1397/10/01
Expected recruitment end date
2019-03-19, 1397/12/28
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigation the effect of oral nicorandil on arrhythmia rate in patients undergoing angioplasty

Public title
The effect of nicorandil on arrhythmia
Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Having a definite diagnosis of myocardial infarction

Exclusion criteria:

Cardiogenic shock Previous use of nicorandil Undergoing cardiopulmonary resuscitation

Age

From **20 years** old to **75 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization with blocks of 10. The patients will be randomly assigned into 2 groups of 50. Considering the sample size of 100 (50 patients in nicorandil group and 50 patients in placebo group) , 10 blocks with 10 people will be selected; in each block there will be 5 cards of nicorandil group and 5 cards of placebo group. So by selecting each block, 5 people will be assigned into each group.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient's physician wont be aware of patients assignment into study groups. Drug and placebo will be similar in shape and size; so the patients are blinded.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zahedan University of Medical Sciences

Street address

Zahedan University of Medical Sciences and Health Services campus, Khalije Fars Blv, Doctor Hesabi Sq, Zahedan

City

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Province

Sistan-va-Balouchestan

Postal code

9916789547

Approval date

2018-02-07, 1396/11/18

Ethics committee reference number

IR.ZAUMS.REC.1396.356

Health conditions studied

1

Description of health condition studied

Myocardial infarction

ICD-10 code

I21

ICD-10 code description

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

Primary outcomes

1

Description

Arrhythmia

Timepoint

After angiography for 48 hours

Method of measurement

By evaluating the electrocardiogram by cardiologist

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Receiving 20 mg nicorandil orally twice a day since admission till discharge

Category

Treatment - Drugs

2

Description

Control group: Receiving nicorandil placebo twice a day since admission till discharge

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali Ebne Abi Taleb Hospital

Full name of responsible person

Hesam Mullazehi

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zahedan 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
Zahedan University of Medical Sciences
Full name of responsible person
Hesam Mullazehi
Position
Cardiology resident
Latest degree
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be 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