

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Aug 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

Country

Iran (Islamic Republic of)

Phone

+98 54 3329 5715

Email address

h.mullazehi.med@zaums.ac.ir

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

Zahedan

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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Khalije Fars Blv, Zahedan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Mohsen Taheri

Street address

Vice chancellor for research, Zahedan University of Medical Sciences, Zahedan

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Dr.Taheri@zaums.ac.ir

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 Mullazehe

Position

Cardiology resident

Latest degree

Medical doctor

Other areas of specialty/work

Cardiology

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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