

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Efficacy of short term prescription of nicorandil on in-hospital outcomes of patients who admitted because of acute coronary syndrome without ST elevation

Protocol summary

Summary

In order to consider the efficacy of Nicorandil addition to common treatments, 252 patients are chosen among the patients suffering from acute coronary syndrome without ST elevation, who are admitted in Heart Center. Firstly, all of them are put in heart monitoring for 48 hours. Then, they are divided in two groups randomly. One group is treated by the common treatments like anti-thrombotic, anti-platelet and painkiller. Another group is put in Nicorandil in addition to these treatments. In the patients' primary ECG, Myocardial Infarction with ST elevation or Left Bundle Branch Block should not be seen. These patients are visited during hospitalization daily by researcher. Both researcher and patients are not aware of prescription. There are the response criteria to treatment, which are recorded, including the number of chest pain episode, arrhythmia, the echocardiography characters, the amount of increasing in myocardial enzymes as well as the number of hospitalization days. The results are recorded in special forms and considered by a statistics expert.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201202189067N1**
Registration date: **2012-03-01, 1390/12/11**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-03-01, 1390/12/11

Registrant information

Name

Sara Jadbabaei

Name of organization / entity

Kermanshah University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

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jadbabaei@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Sciences, Vice-chancellor for Research and technology

Expected recruitment start date

2012-02-04, 1390/11/15

Expected recruitment end date

2012-05-04, 1391/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of short term prescription of nicorandil on in-hospital outcomes of patients who admitted because of acute coronary syndrome without ST elevation

Public title

Efficacy of nicorandil in acute coronary syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criterion: Non ST elevation acute coronary syndrome. Exclusion criteria: myocardial infarction with

ST levation and Left Bundle Branch Block

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 252

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kermanshah university of medical sciences and health services

Street address

Shahid Beheshti Blvd

City

Kermanshah

Postal code

671673159

Approval date

2012-01-31, 1390/11/11

Ethics committee reference number

7/420/61202/پ

Health conditions studied

1

Description of health condition studied

Acute coronary syndrome

ICD-10 code

I20_I25

ICD-10 code description

Ischaemic heart disease

Primary outcomes

1

Description

Response treatment

Timepoint

During hospitalization daily

Method of measurement

Physician visit

Secondary outcomes

1

Description

Clinical side effect

Timepoint

During hospitalization daily

Method of measurement

Physician visit

Intervention groups

1

Description

Interventional group: Oral Nicorandil is started at first day of admission 20 mg BID in addition to common treatment, then continued during hospitalization until last day.

Category

Treatment - Drugs

2

Description

Control group: identical to that of common treatment including antithrombotic, antiplatelet and analgesics.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Ali hospital

Full name of responsible person

Sara Jadbabaei

Street address

Imam Ali hospital, Shahid Beheshti Blvd

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Kermanshah University of Medical Sciences and Health Services

Full name of responsible person

Dr. Farid Najafi

Street address

Shahid Beheshti Blvd, Kermanshah University of
Medical Sciences and Health Services

City

Kermanshah

Grant name**Grant code / Reference number****Is the source of funding the same sponsor
organization/entity?**

Yes

Title of funding source

Vice chancellor for research, Kermanshah University of
Medical Sciences and Health Services

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Kermanshah university of medical sciences and
health services

Full name of responsible person

Sara Jadbabaei

Position

Cardiology resident

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty