

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of Loratadine effect on the rate of rehospitalization and recurrent angina in patients with acute coronary syndrome

Protocol summary

Summary

This randomized trial evaluated the effect of Loratadine on the rate of readmission and the incidence of recurrent angina in patients with acute coronary syndrome in 200 patients diagnosed with acute coronary syndrome (Bravwald class 2 and 3) admitted in the CCU ward of Ali Ibn Abi Talib Hospital (AS), Rafsanjan. The patients in the control group received Aspirin plus Heparin plus a beta-blocker. In the intervention group, Loratadine (oral tablet 10 mg daily for a month) was added to the medication of the control group. The frequency of recurrent angina and readmission were measured on a weekly basis and compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138903131061N7**

Registration date: **2010-07-03, 1389/04/12**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-07-03, 1389/04/12

Registrant information

Name

Reza Vazirinejad

Name of organization / entity

Rafsanjan University of Medical Sciences

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Iran (Islamic Republic of)

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+98 39 1822 0097

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pejoheshi@rums.ac.ir

Recruitment status

Recruitment complete

Funding source

Rafsanjan University of Medical Sciences

Expected recruitment start date

2009-03-21, 1388/01/01

Expected recruitment end date

2010-05-22, 1389/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Loratadine effect on the rate of rehospitalization and recurrent angina in patients with acute coronary syndrome

Public title

Loratadine effect on the rate of rehospitalization and recurrent angina in patients with acute coronary syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: class 2 and 3 of Braunwald criteria
Exclusion criteria: prior history of hospitalization due to acute coronary syndrome, presence of liver disease, using antihistamines drugs such drugs as Cimetidine, Erythromycin, Clarithromycin, anti-fungal group and Fluoxetine

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics in medical research committee of Rafsanjan University of Medical Sciences

Street address

Central organization of Rafsanjan University of Medical Sciences, Imam Ali Boulevard, Rafsanjan,

City

Rafsanjan

Postal code

Approval date

2009-03-19, 1387/12/29

Ethics committee reference number

9/20/2097

Health conditions studied

1

Description of health condition studied

acute coronary syndrome

ICD-10 code

I24.9

ICD-10 code description

Acute ischaemic heart disease, unspecified

Primary outcomes

1

Description

Readmission

Timepoint

Baseline, the first, second , third, and fourth week after the intervention

Method of measurement

Visual analog scale of readmission

2

Description

Recurrent angina

Timepoint

Baseline, the first, second , third, and fourth week after the intervention

Method of measurement

Descriptive scale of chest pain

Secondary outcomes

1

Description

Side effects of loratadine

Timepoint

Baseline, the first, second , third, and fourth week after the intervention

Method of measurement

Descriptive scale of symptoms such as headache, insomnia, weakness

Intervention groups

1

Description

Intervention group: Loratadine, oral tablet, 10 mg daily for a one month course + Aspirin, oral tablet 80 mg daily + Metoral, oral tablet 25-50 mg towise in day

Category

Treatment - Drugs

2

Description

Control group: Aspirint oral tablet 80 mg daily + Metoralt oral tablet 25-50 mg twice in day

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Cardiology, Ali ibn Abi Talib (AS) hospital, Rafsanjan University of Medical Sciences

Full name of responsible person

Street address

City

Rafsanjan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Dr. Hossein Azin

Street address

Rafsanjan University of Medical Sciences, Emam ali Blvd.

City

Rafsanjan

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

Yes

Title of funding source

Rafsanjan University of Medical Sciences

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

Rafsanjan University of Medical Sciences

Full name of responsible person

Dr. Ali Esmaeeli Nadimi

Position

Board of Cardiology

Other areas of specialty/work**Street address**

Ali ibn Abi Talib (AS) hospital, department of cardiology

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Rafsanjan University of Medical Sciences

Full name of responsible person

Monavar Naderi

Position

BS/labrarin

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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*