Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 (Bravnvald 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
Country
Iran (Islamic Republic of)
Phone
+98 39 1822 0097
Email address
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 towice 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
City
Rfsanjan
Postal code
00989131913649
Phone
+98 39 1822 0001
Fax
Email
dr_nadimi@yahoo.co.uk
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
Other areas of specialty/work
Street address
Rafsanjan University of Medical Sciences, Emam ali Blvd.
City
Rafsanjan
Postal code
7717933777
Phone
+98 39 1822 0086
Fax
+98 39 1822 0086
Email
monanaderi56@yahoo.com
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