

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

Comparison of the effect of Atorvastatin and rosuvastatin Treatment on the Levels of 25 Hydroxyvitamin D in patient with acute coronary syndrome

Protocol summary

Study aim

Comparison the effect of atorvastatin and rosuvastatin on 25-hydroxy vitamin D level in patients with acute myocardial infarction

Design

Clinical trial, block Randomization, parallel groups, blinded outcome, 40 patients in each group, phase 4

Settings and conduct

Patients with acute myocardial infarction are referred to Neyshabur 22 Bahman Hospital, the heart center of the city. After being diagnosed by a cardiologist, they are randomly assigned to one of two study groups and their recommended anti-lipid treatment begins. Blood samples are taken immediately after admission, 12 hours after and 2 weeks after the patient.

Participants/Inclusion and exclusion criteria

Acute Myocardial Infarction Patients Based on ECG Findings, Laboratory Results, and Chest Pain

Intervention groups

One group atorvastatin tablets and the other group rosuvastatin.

Main outcome variables

25-hydroxy vitamin D level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190902044673N1**

Registration date: **2019-11-07, 1398/08/16**

Registration timing: **retrospective**

Last update: **2019-11-07, 1398/08/16**

Update count: **0**

Registration date

2019-11-07, 1398/08/16

Registrant information

Name

Hasan Ghodsi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2018-09-23, 1397/07/01

Actual recruitment start date

2017-02-19, 1395/12/01

Actual recruitment end date

2019-01-05, 1397/10/15

Trial completion date

2019-01-05, 1397/10/15

Scientific title

Comparison of the effect of Atorvastatin and rosuvastatin Treatment on the Levels of 25 Hydroxyvitamin D in patient with acute coronary syndrome

Public title

The effect of Atorvastatin and rosuvastatin on the Levels of 25 Hydroxyvitamin D

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Acute Coronary Syndrome with: chest pain, ECG ST elevation and Troponin Enzyme rising

Exclusion criteria:
Diabetes Mellitus Take anti-lipid drugs during three past months

Age
From **18 years** old to **75 years** old

Gender
Both

Phase
4

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **80**
Actual sample size reached: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, we will prepare 4 leaves that are typed on the two leaves of the letter A (atrostatin) and on the other two leaves of the letter R (rosuvastatin) and draw one card for each patient, without the card being drawn. Insert. At the end of each block we have an equal number of people who received treatment A or treatment R. This process continues until the patient has been included in the study as a sample size. To make our randomization process unpredictable, we use a person (the secretary) to make this assignment and provide conditions for both the patient and the physician to determine the size of the block and the type of treatment received. Be aware and blindness will occur. If each drug contains 60 similar packages, only the letters A for atrostatin and R for rosuvastatin are written on the packaging, and only by the researcher himself. It will know the contents of the packaging and the type of medication.

Blinding (investigator's opinion)

Double blinded

Blinding description

Both the patient and the physician are not aware of medications and their sequences and so blindness is occurred.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Neyshabur University of Medical Sciences

Street address

Janbazan Blvd- Neyshabur

City

Neyshabur

Province

Razavi Khorasan

Postal code

9315833333

Approval date

2016-03-09, 1394/12/19

Ethics committee reference number

lr.num.s.rec.1394.19

Health conditions studied

1

Description of health condition studied

Patient with Acute Coronary Syndrome

ICD-10 code

I21

ICD-10 code description

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

Primary outcomes

1

Description

25-hydroxy vitamin D level

Timepoint

At the beginning ,the first 24 hours of hospitalization, two months after admission

Method of measurement

25-hydroxy vitamin D level in blood

Secondary outcomes

empty

Intervention groups

1

Description

The first group of intervention: These patients were randomly subjected to either a single dose of 80 mg Atorvastatin as a secondary prevention treatment plus a routine treatment regimen for 8 weeks at nights. In total, 10 ml blood samples were taken at the time of admission to the emergency department; moreover, 10 ml fasting blood samples were collected within the first 24 h and 2 months after the patients were admitted to the hospital. In addition, blood samples were analyzed for biochemical parameters.

Category

Treatment - Drugs

2

Description

The second group of intervention: These patients were randomly subjected to either a single dose of 40 mg Rosuvastatin as a secondary prevention treatment plus a routine treatment regimen for 8 weeks at nights. In total, 10 ml blood samples were taken at the time of admission to the emergency department; moreover, 10 ml fasting blood samples were collected within the first 24 h and 2 months after the patients were admitted to the hospital. In addition, blood samples were analyzed for biochemical parameters.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

22 Bahman -Neyshabur Hospital

Full name of responsible person

Samaneh Tabaei

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22 Bahman Hospital- Emam Khomeini Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Neyshabour University of Medical Sciences

Full name of responsible person

Seyyed Morteza Shamshirgaran

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sci@nums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor

organization/entity?

Yes

Title of funding source

Neyshabour 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

Neyshabour University of Medical Sciences

Full name of responsible person

Samaneh Tabaei

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Cardiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Latest degree

Specialist

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Not applicable