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 atrovastatin 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 atrovastatin 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

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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
Ir.nums.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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
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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