Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Effect of Atorvastatin versus Rosuvastatin on level of inflammatory markers and low density lipoprotein-cholesterol (LDL) in Patients with acute coronary syndrome: double blind randomize control trial

Protocol summary

Study aim
Comparison of the effect of atrovstatin and rosuvastatin on the level of inflammatory markers

Design
double blind randomize control trial, parallel group trial with blinded outcome assessment.

Settings and conduct
Eighty-four patients with acute coronary syndrome will be selected for study at CCU 22 Bahman Neyshabur Hospital. Before starting the study, sampling will be done, then patients will be randomly assigned to receive a single dose of 40 mg rosuvastatin or atrostatin 80 mg daily after dinner plus a routine treatment regimen. The drugs are encoded and encoded by the secretary inside the same envelopes, and all researchers, doctors, staff and nurses and the Committee on Safety and Security are unaware of the contents of the envelopes. Blood samples are taken two months after the patients and evaluated for inflammatory markers.

Participants/Inclusion and exclusion criteria
Diagnosis of acute coronary syndrome based on clinical signs and ECG and serum markers Factors Affecting Inflammation and Lipid Profile

Intervention groups
In one group of patients atrovstatin (80mg) and in the other group rosovastatin (40mg) Prescribed

Main outcome variables
ApoA; ApoB; TNF α; IL-6; MCP-1; INF-γ; IL-10; HDL; LDL; TG

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190903044682N1**
Registration date: **2019-12-26, 1398/10/05**
Registration timing: **retrospective**

Last update: **2019-12-26, 1398/10/05**
Update count: **0**

Registration date
2019-12-26, 1398/10/05

Registrant information

Name
Seyedeh samaneh Tabaee

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 51 4225 5524

Email address
tabaees@nums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-09-01, 1398/06/10

Expected recruitment end date
2019-09-11, 1398/06/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of Atorvastatin versus Rosuvastatin on level of inflammatory markers and low density lipoprotein-cholesterol (LDL) in Patients with acute coronary syndrome: double blind randomize control trial

Public title

statin and inflamation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Acute coronary syndrome based on clinical signs and ECG and serum markers

Exclusion criteria:

renal failure Liver failure Immunosuppressants, corticosteroids or potent inhibitors of cytochrome P450 3A4, pentoxifylline, silostazole, glucosamine, berberine barberry extract Having underlying inflammatory or infectious diseases Left Schiff's Leukostosis TG>400 CHF with NYHA III or IV Having a history of diseases that cause malabsorption syndromes Uncontrolled blood pressure Evidence of endocrine or metabolic disease affecting lipid profile

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

Subjects with inclusion criteria were randomly divided into two groups: atrostatin and rosuvastatin. For this purpose, we randomly divide the participants into atrostatin and simvastatin groups using 4-way randomized blockade. In this study, we will prepare four 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.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, atrovstatin and rosuvastatin are poured into similar envelopes by a secretary and then coded, envelopes are coded, patients are assigned an envelope in order of study, and the envelope code is recorded for each patient. Participants, all researchers, other cardiologists, CCU nurses and cardiologists, laboratory staff, data collectors, patients with phone calls for follow-up, and the Committee on Safety and Data Monitoring, and The person drafting the article is not aware of the contents of the envelopesatment received and face blindness

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Neyshabour University of Medical Sciences

Street address

University Pardis, Shen Shui Street,

City

Neyshabur

Province

Razavi Khorasan

Postal code

9319116911

Approval date

2016-03-09, 1394/12/19

Ethics committee reference number

Ir.nums.rec.1394.22

Health conditions studied

1

Description of health condition studied

Levels of inflammatory markers

ICD-10 code

ICD-10 code description

موضوع مطالعه یک بیماری نیست

Primary outcomes

1

Description

blood levels of inflammatory markers

Timepoint

Before starting the study and 60 days later beginning

Method of measurement

Laboratory measurement by ELISA

Secondary outcomes

1

Description

Lipid profile

Timepoint

Before the intervention and at the end of the

intervention

Method of measurement

Laboratory measurement with Pars test kit with Autoanalyzer bt 3000

2

Description

Blood levels of inflammatory markers

Timepoint

Before the intervention and at the end of the intervention

Method of measurement

Laboratory tests

Intervention groups

1

Description

Intervention group: atrovastetin is a drug manufactured by Abidi Pharmaceutical Company at a dose of 80 mg once daily after dinner for 60 days.

Category

Treatment - Drugs

2

Description

Intervention group: Rosvastatin is a drug manufactured by Abidi Pharmaceutical Company at a dose of 40 mg once daily after dinner for 60 days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

22 Bahman Hospital

Full name of responsible person

Seyedeh Samaneh Tabaee

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Neyshabour University of Medical Sciences

Full name of responsible person

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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

Seyedeh Samaneh Tabaee

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Cardiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available