

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Comparison of the effects of different doses of Atorvastatin on Plasma homocysteine levels in male Patients with Coronary Atherosclerosis

Protocol summary

Summary

In this study we investigated the effect of different doses of atorvastatin on plasma concentration of homocysteine in male patients with coronary heart disease. In a double-blind clinical trial conducted from April to September 2007, we enrolled 52 male patients who were hospitalized in Mazandaran heart center due to acute coronary syndrome. Patients with unstable angina, sensitivity to statins, diseases of hepatobiliary system, serum creatinine concentrations $\geq 175 \mu\text{mol/l}$ (2.0 mg/dl), left anterior descending artery involvement, history of using QT interval prolongation and P450 suppressant drugs and the patients with unreasonable high creatine kinase were excluded. Patients who met including criteria were divided into three groups randomly and they received 20, 40, and 80 mg atorvastatin daily for six months. Laboratory assessments for measuring the level of Homocysteine were done before and 1, 3 and 6 months after the treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013071614018N1**

Registration date: **2013-08-18, 1392/05/27**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-08-18, 1392/05/27

Registrant information

Name

Safoora Masoumi

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 15 1241 4858

Email address

safoora.masoumi@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Sciences

Expected recruitment start date

2007-04-01, 1386/01/12

Expected recruitment end date

2007-10-01, 1386/07/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of different doses of Atorvastatin on Plasma homocysteine levels in male Patients with Coronary Atherosclerosis

Public title

Comparison of the effects of different doses of Atorvastatin on blood homocysteine levels in male Patients with heart disease.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Male; Stable; Acute Coronary Syndrome; Documented atherosclerotic lesions in Angiography ; Refused to do Coronary Artery Bypass Graft or Angioplasty Exclusion criteria: Female; Unstable Angina; Sensitivity to Statins ; Diseases of hepatobiliary system ; Serum creatinine concentrations $\geq 175 \mu\text{mol/l}$ (2.0 mg/dl) ; Left anterior descending artery involvement

; History of using QT interval prolongation and P450 suppressant drugs ; unreasonable high creatine kinase

Age

No age limit

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 52

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Mazandaran University of Medical Sciences

Street address

Juybar interaction ,Imam square

City

Sari

Postal code**Approval date**

2006-06-12, 1385/03/22

Ethics committee reference number

85/3/22

Health conditions studied**1****Description of health condition studied**

Ischemic Heart Disease

ICD-10 code

I21

ICD-10 code description

Acute myocardial infarction

Primary outcomes**1****Description**

Homocysteine levels

Timepoint

1, 3 and 6 months

Method of measurement

Blood sampling

Secondary outcomes**1****Description**

Side effects of drug

Timepoint

1,3,6 months and whenever the patients complaint

Method of measurement

Clinical examination

Intervention groups**1****Description**

The second group recieved 80 mg /day Atorvastatin for six months

Category

Treatment - Drugs

2**Description**

The first group recieved 20 mg/day Atorvastatin for six months

Category

Treatment - Drugs

3**Description**

The second group recieved 40 mg/day Atorvastatin for six months.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Mazandaran Heart Center

Full name of responsible person

Dr Keyvan Yousefnejad

Street address

Mazandaran Heart Center, Artesh BLVD

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr yousefnejad

Street address

Deputy of research, Moallem suare, Moallem street

City

Sari

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mazandaran 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

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Safoora Masoumi

Position

MD

Other areas of specialty/work

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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