

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparing effectiveness of high dose atorvastatin versus low dose atorvastatin in cardiovascular outcome after Percutaneous Coronary Intervention (PCI) in patients with stable angina

Protocol summary

Summary

Main objective: Comparing effectiveness of high dose atorvastatin versus low dose atorvastatin in cardiovascular outcome after percutaneous coronary intervention (PCI) in patients with stable angina, for prevention of major cardiovascular events- Method: randomized clinical trial, double blinded, single center, drug intervention- Control group: atorvastatin, tablet 10 mg twice per day oral (standard treatment)- Intervention group: atorvastatin, tablet 40 mg twice per day oral- Inclusion criteria: patients with stable angina that nominated for coronary angioplasty- Exclusion criteria: acute coronary syndrome (unstable angina, non ST elevation myocardial infarction, ST elevation myocardial infarction), bare stent angioplasty, balloon angioplasty, angioplasty on saphenous vein graft, liver disease- Volume: 469 patients, 6 month follow up- Primary outcome measure: major adverse cardiac and cerebrovascular events, all cause mortality, stroke, target lesion revascularization, target vessel revascularization, acute coronary syndrome, at least 3 times increase of liver and or muscular enzymes- Secondary outcome measure: total cholesterol (end of study), LDL (end of study), HDL (end of study), triglyceride(end of study), total cholesterol to HDL (end of study)

General information

Acronym

HAT-COP

IRCT registration information

IRCT registration number: **IRCT2016060418741N2**

Registration date: **2016-06-14, 1395/03/25**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-06-14, 1395/03/25

Registrant information

Name

Babak Bagheri

Name of organization / entity

Mazandaran university of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 3332 4002

Email address

bbagheri@mazums.ac.ir

Recruitment status

Recruitment complete

Funding source

Mazandaran Univesity of Medical Sceinces

Expected recruitment start date

2012-04-20, 1391/02/01

Expected recruitment end date

2015-01-21, 1393/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing effectiveness of high dose atorvastatin versus low dose atorvastatin in cardiovascular outcome after Percutaneous Coronary Intervention (PCI) in patients with stable angina

Public title

effect of high dose of atorvastatin after angioplasty in

patients with stable angina

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: patients with stable angina that nominated for coronary angioplasty Exclusion criteria: acute coronary syndrome (unstable angina, non ST elevation myocardial infarction, ST elevation myocardial infarction); bare stent angioplasty; balloon angioplasty; angioplasty on saphenous vein graft; liver disease

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **469**

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

Valiasr highway, Imam square, Sari

City

Sari

Postal code

Approval date

2013-01-23, 1391/11/04

Ethics committee reference number

91168

Health conditions studied

1

Description of health condition studied

stable angina

ICD-10 code

I25

ICD-10 code description

Chronic ischaemic heart disease

Primary outcomes

1

Description

major adverse cardiovascular and cerebrovascular events

Timepoint

6 month after procedure

Method of measurement

Questionnaire

2

Description

all cause mortality

Timepoint

6 month after procedure

Method of measurement

Questionnaire

3

Description

myocardial infarction

Timepoint

6 month after procedure

Method of measurement

Questionnaire

4

Description

stroke

Timepoint

6 month after procedure

Method of measurement

Questionnaire

5

Description

target lesion revascularization

Timepoint

6 month after procedure

Method of measurement

Questionnaire

6

Description

target vessel revascularization

Timepoint

6 month after procedure

Method of measurement

Questionnaire

7

Description

acute coronary syndrome

Timepoint

6 month after procedure

Method of measurement

Questionnaire

8

Description

at least 3 times increase of liver enzyme

Timepoint

3 , 6 month after procedure

Method of measurement

miligram per deciliter

9

Description

at least 3 times increase of muscular enzyme

Timepoint

3 , 6 month after procedure

Method of measurement

miligram per deciliter

Secondary outcomes

1

Description

low density lipoprotein (LDL)

Timepoint

end of study

Method of measurement

miligram per deciliter

2

Description

total cholesterol

Timepoint

end of study

Method of measurement

miligram per deciliter

3

Description

high density lipoprotein (HDL)

Timepoint

end of study

Method of measurement

miligram per deciliter

4

Description

triglyceride

Timepoint

end of study

Method of measurement

miligram per deciliter

5

Description

total cholesterol to HDL

Timepoint

end of study

Method of measurement

miligram per deciliter

Intervention groups

1

Description

Intervention group: atorvastatin- tablet 40 mg twice per day up to 6 month

Category

Treatment - Drugs

2

Description

Control group: standard treatment- atorvastatin- tablet 10 mg twice per day up to 6 month

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hospital of Fatemeh Zahra

Full name of responsible person

Tohid Rahimi

Street address

Artesh boulevard, Sari

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Ahmad Ali Enayati

Street address

Valiasr high way,Imam square, Sari

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

Tohid Rahimi

Position

resident of cardiology

Other areas of specialty/work

Street address

Valiasr high way, Imam square, Sari

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t.rahimi59@yahoo.com

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Hospital of Fatemeh Zahra

Full name of responsible person

Tohid Rahim

Position

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Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

Name of organization / entity

Hospital of Fatemeh Zahra

Full name of responsible person

Tohid Rahimi

Position

resident of cardiology

Other areas of specialty/work

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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