

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparing two different doses of Atorvastatin for decrease the level of LDL in ACS patient and determinate the effective dose of drug.

Protocol summary

Study aim

Determine the effective dose of Atorvastatin in the ACS (acute coronary syndrome) patients in Heshmatieh hospital in 1397

Design

Controlled clinical trial, randomized, single blinded, parallel group, in 60 patients. Randomization was simple.

Settings and conduct

In this study, a population of 60 ACS (acute coronary syndrome) patients admitted to the CCU (coronary care unit) section of Hashamtayeh Sabzevar Hospital will be studied. So that all patients will be taken of fat profile tests and echocardiography when they are admitted. One group received three months of treatment with 40 mg of atorvastatin daily and the other group will be treated with atorvastatin 80 mg daily for three months. After three months, the patients will be checked twice for a fat profile by referring to the cardiologist and the LDL (Low Density Lipoprotein) reduction in both groups will be recorded. Ultimately, reduction of LDL cholesterol will be compared in both case and control groups.

Participants/Inclusion and exclusion criteria

login: ACS (acute coronary syndrome) patients who are admit in CCU (coronary care unit) in Heshmatie hospital
Exit: The normal coronary patients The patients who are more than 75 years old The patients who are using Fibrate drugs in the same time The patients who are living in the villages and disable for follow up

Intervention groups

Case group: In this group patients will take 40 milligram Atorvastatin daily. Control group: In this group patients will take 80 milligram Atorvastatin daily.

Main outcome variables

Determine the effective dose of Atorvastatin in ACS (acute coronary syndrome) patients Determine the amount of reduction of LDL (Low Density Lipoprotein) in patients.

General information

Reason for update

We deleted the study of MDR1 polymorphism, Because of facing with some problems in the collecting the data. We did this after approving the change in the research council of Sabzevar university of medical sciences.

Acronym

IRCT registration information

IRCT registration number: **IRCT20140921019240N4**
Registration date: **2018-06-08, 1397/03/18**
Registration timing: **prospective**

Last update: **2021-12-07, 1400/09/16**

Update count: **1**

Registration date

2018-06-08, 1397/03/18

Registrant information

Name

Omid Gholami

Name of organization / entity

Sabzevar University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-22, 1397/04/01

Expected recruitment end date

2018-12-21, 1397/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty
Trial completion date
empty

Scientific title
Comparing two different doses of Atorvastatin for decrease the level of LDL in ACS patient and determinate the effective dose of drug.

Public title
Comparing two different doses of Atorvastatin for decrease the level of LDL in ACS patient.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

ACS (acute coronary syndrom) patients who are admit in CCU (coronary care unit) in Heshmatie hospital

Exclusion criteria:

The normal coronary patients The patients who are more than 75 years old The patients who are using Fibrate drugs in the same time The patients who are living in the villages and disable for follow up

Age
To **75 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization From the beginning of the study, the names of the patients will be document in the table. The patients with odd number will be in A group and the patients with even number will be in B group.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this one-blind clinical trial, only subjects were unaware of the study procedure.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee

Ethics committee of Sabzevar University of Medical Sciences

Street address

Ethics committee of Sabzevar University of Medical Sciences, Shohadaie Hastehi Blvd, Sabzevar

City
Sabzevar

Province
Razavi Khorasan

Postal code
9617913112

Approval date
2018-02-26, 1396/12/07

Ethics committee reference number
IR.Medsab.Rec.1396.153

Health conditions studied

1

Description of health condition studied
acute coronary syndrome

ICD-10 code
I24.9

ICD-10 code description
Acute ischemic heart disease, unspecified

Primary outcomes

1

Description
Low density lipoprotein

Timepoint
At the start of study & 3 months later

Method of measurement
Blood test

2

Description
MDR1 (Multi-Drug Resistance) gene polymorphism

Timepoint
At the start of study

Method of measurement
Polymerase Chain Reaction

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The intervention group received three months of treatment with 40 mg of atorvastatin daily from the start of study. Atorvastatin product by Abidi Pharmaceutical Company.

Category
Treatment - Drugs

2

Description

Control group: The control group will be treated with atorvastatin 80 mg daily for three months. Atorvastatin product by Abidi Pharmaceutical Company.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Heshmatie hospital

Full name of responsible person

Nafiseh Khalilzadeh

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Omid Gholami

Street address

Sabzevar University of Medical Science, Deputy of Research and Technology of Sabzevar University of Medical Sciences

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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

Sabzevar 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

Sabzevar University of Medical Sciences

Full name of responsible person

Nafiseh Khalilzadeh

Position

Student (Intern)

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

Contact

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Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Person responsible for updating data

Contact

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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

After unidentifiable people, you can shared the all of personal data.

When the data will become available and for how long

The start of access period is 6 months after publish results.

To whom data/document is available

Researchers working in academic and scientific institutions and industry workers.

Under which criteria data/document could be used

Using the results of this study with the source is allowed.

From where data/document is obtainable

Dr.Omid Gholami Sabzevar University of Medical Science
omid693@yahoo.com

What processes are involved for a request to access data/document

We can submit data if a person with the specific organizational affiliation, submit a written request.

Comments