Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of ezetimibe and atorvastatin treatment versus atorvastatin alone on Major Adverse Cardiac Events (MACE) after elective percutaneous coronary intervention (PCI)

Protocol summary

Study aim

Comparison of ezetimibe and atorvastatin treatment versus atorvastatin alone on Major Adverse Cardiac Events (MACE) after elective percutaneous coronary intervention (PCI) in Jorjani Angiogeraphy Center of Shahid Mohammadi Hospital

Design

In this study, 224 patients who refer to the Jorjani Center of Shahid Mohammadi Hospital in Bandar Abbas for PCI will be included in the study randomly if they have all the inclusion criteria and none of the exclusion criteria. They are then randomly divided into intervention and control groups.

Settings and conduct

This is a double blind clinical trial on patients refer to the Jorjani Center of Shahid Mohammadi Hospital in Bandar Abbas. Patients in the first group receive atorvastatin 40 mg and ezetimibe 10 mg daily. In the second group, the placebo is given in the same dose as in the original package, with the same shape, color and size, and in a manner, that is not differentiated from the original drug. Medications will be packaged in pre-prepared packages to patients so that patients and people who record the results of the study will be unaware of how the patients will be grouped.

Participants/Inclusion and exclusion criteria

Each patient who refers for PCI will be included if he/she meets all the inclusion criteria such as having normal hepatic enzymes and having negative troponin and does not meet any of the exclusion criteria such as having Inflammatory and rheumatologic diseases.

Intervention groups

Patients in the first group (intervention) receive atorvastatin 40 mg and ezetimibe 10 mg daily. In the second group (control), patients will receive atorvastatin 40 mg and 10 mg placebo instead of ezetimibe on a daily basis.

Main outcome variables

Myocardial infarction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171028037047N1**
Registration date: **2018-06-22, 1397/04/01**
Registration timing: **registered_while_recruiting**

Last update: **2018-06-22, 1397/04/01**
Update count: **0**

Registration date

2018-06-22, 1397/04/01

Registrant information

Name

badri bijani

Name of organization / entity

Cardiovascular Research Center, Hormozgan University of Medical Sciences, Bandar Abbas, Iran

Country

Iran (Islamic Republic of)

Phone

+98 76 3333 7379

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-04, 1396/11/15

Expected recruitment end date

2018-08-06, 1397/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of ezetimibe and atorvastatin treatment versus atorvastatin alone on Major Adverse Cardiac Events (MACE) after elective percutaneous coronary intervention (PCI)

Public title

Comparison of ezetimibe and atorvastatin treatment versus atorvastatin alone on Major Adverse Cardiac Events

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who are candidates for elective PCI Having normal hepatic enzymes Having negative troponin Having LDL values greater than 100 mg / dL

Exclusion criteria:

Having Inflammatory and rheumatologic diseases Having Infectious diseases Having malignancies Having high creatinine levels Having abnormal liver enzymes Pregnancy and lactation Use of NSAIDs Patient's dissatisfaction with participating in the study Having ejection fraction below 30 (EF < 30) Having myocardial infarction in the last month The increase in troponin after PCI more than 5 times higher than normal maximum of 99 percentile

Age

No age limit

Gender

Both

Phase

4

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **224**

Randomization (investigator's opinion)

Randomized

Randomization description

In randomized manner, every patient who goes to PCI will be included in the study if they have all the inclusion criteria and no exclusion ones. Then by tossing coin they will be randomly divided into intervention and non intervention groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients in the first group receive atorvastatin 40 mg and ezetimibe 10 mg daily. In the second group, the placebo is given in the same dose as in the original package, with the same shape, color and size, and in a manner that is not differentiated from the original drug. Medications will be packaged in pre-prepared packages to patients so that patients and people who record the results of the study will be unaware of how the patients will be grouped.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hormozgan University of Medical Sciences

Street address

Shahid Chamran Blvd.

City

Bandar Abbas

Province

Hormozgan

Postal code

7916613885

Approval date

2018-01-06, 1396/10/16

Ethics committee reference number

HUMS.REC.1396.133

Health conditions studied

1

Description of health condition studied

Myocardial infarction

ICD-10 code

I21

ICD-10 code description

ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction

Primary outcomes

1

Description

Myocardial infarction

Timepoint

At intervals of 24 hours after PCI and one month after PCI

Method of measurement

ECG, hospital records, blood tests and imaging

Secondary outcomes

1

Description
Unstable angina
Timepoint
At intervals of 24 hours after PCI and one month after PCI
Method of measurement
ECG, hospital records, blood tests and imaging

2

Description
Death rate due to heart disease
Timepoint
At intervals of 24 hours after PCI and one month after PCI
Method of measurement
Hospital records

3

Description
Stroke rate
Timepoint
At intervals of 24 hours after PCI and one month after PCI
Method of measurement
ECG, hospital records, blood tests and imaging

4

Description
Stent thrombosis
Timepoint
At intervals of 24 hours after PCI and one month after PCI
Method of measurement
ECG, hospital records, blood tests and imaging

5

Description
CRP value
Timepoint
At intervals of 24 hours after PCI and one month after PCI
Method of measurement
Blood tests

Intervention groups

1

Description
Intervention group: Patients in this group receive atorvastatin 40 mg and ezetimibe 10 mg daily
Category
Treatment - Drugs

2

Description
Control group: Patients in this group receive atorvastatin 40 mg and placebo 10 mg daily. The placebo is given in the same dose as in the original package, with the same shape, color and size, and in a manner, that is not differentiated from the original drug
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Jorjani Angiogeraphy Center of Shahid Mohammadi Hospital of Bandar Abbas
Full name of responsible person
Shahin Abbas Zadeh
Street address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bandare-abbas University of Medical Sciences
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Grant name
Vice chancellor of research, Hormozgan University of Medical Sciences
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Bandare-abbas 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
Bandare-abbas University of Medical Sciences
Full name of responsible person
Shahin Abbas Zadeh
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for updating data

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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
No - There is not a plan to make this available