

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 May 2026

Comparing the effect of preprocedural loading dose of Arorvastatin vs Rrosuvastatin on prevalence of no-reflow and low TIMI flow in patients with ST elevation myocardial infarction undergoing primary percutaneous intervention

Protocol summary

Study aim

Comparing the effect of preprocedural loading dose of Atorvastatin vs Rosuvastatin on prevalence of no-reflow and low TIMI flow in patients with ST elevation myocardial infarction undergoing primary percutaneous intervention

Design

The randomized clinical trial had a control group, parallel groups trial without blinding, simple randomized, design of 160 patients. A random number table will be used for randomization.

Settings and conduct

The study will be done in Madani heart center of Tabriz. Patients will be treated with stat dose of Atorvastatin and Resvostatin before PPCI in emergency department without blinding.

Participants/Inclusion and exclusion criteria

The patients with acute myocardial infarction, regardless of the patients with chronic disease, history of acute myocardial infarction, ischemic heart disease.

Intervention groups

The first group of patients will receive 80 mg of Atorvastatin and the second group, 40 mg of Rosuvastatin.

Main outcome variables

No-reflow phenomen during the procedure, TIMI flow at the end of the procedure and mortality rates during hospitalization will be compared between two (intervention and control) groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200722048166N1**

Registration date: **2021-09-10, 1400/06/19**

Registration timing: **registered_while_recruiting**

Last update: **2021-09-10, 1400/06/19**

Update count: **0**

Registration date

2021-09-10, 1400/06/19

Registrant information

Name

naser khalili

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3387 7616

Email address

dr_nkhalili@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-02, 1400/05/11

Expected recruitment end date

2021-09-22, 1400/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of preprocedural loading dose of Arorvastatin vs Rrosuvastatin on prevalence of no-reflow and low TIMI flow in patients with ST elevation

myocardial infarction undergoing primary percutaneous intervention

Public title

Atorvastatin and Rosuvastatin in myocardial infarction

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patients who are candidates primary percutaneous intervention with acute myocardial infarction with ST-segment elevation are admitted to the emergency department of Madani heart center of Tabriz.

Exclusion criteria:

The patients with chronic disease such as inflammatory diseases, renal failure, a history of collagen and vascular disease, current active infection, blood diseases. The patients with history of acute myocardial infarction or ischemic heart disease. The patients with history of diabetes.

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **160**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, patients are divided into two groups (Atorvastatin & Rosuvastatin) using sealed sachets. The researcher puts drug in the bags and randomly gives one of the sealed bags to each patient.

Blinding (investigator's opinion)

Double blinded

Blinding description

The researcher is the only person who isn't blind in this study. The clinical caregiver randomly delivers packets containing medications to patients. The interventionist monitors and reports outcomes while is unaware of the type of medication that patients are receiving, and the patients are blind to which medication they have received.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Golbad

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East Azarbaijan

Postal code

5166614766

Approval date

2021-08-02, 1400/05/11

Ethics committee reference number

IR.TBZMED.REC.1400.394

Health conditions studied

1

Description of health condition studied

acute myocardial infarction

ICD-10 code

I21

ICD-10 code description

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

Primary outcomes

1

Description

Rate of no-reflow at the during of PPCI

Timepoint

once at the during of the PPCI

Method of measurement

observational and based on individual skills

2

Description

Rate of TIMI flow at the end of PPCI

Timepoint

once at the end of the PPCI

Method of measurement

observational and based on individual skills

Secondary outcomes

1

Description

Rate of mortality

Timepoint

During hospitalization

Method of measurement

Observational

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

Control group: Patients in this group will be treated Atorostatin 80 mg, the first dose will be prescribed in the emergency department and the other doses will be continuous.

Category

Treatment - Drugs

2**Description**

Intervention group: Patients in this group will be treated Resvostatin 40 mg, the first dose will be prescribed in the emergency department and the other doses will be continuous.

Category

Treatment - Drugs

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

Madani heart center of Tabriz

Full name of responsible person

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Web page address**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tabriz 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**

Tabriz University of Medical Sciences

Full name of responsible person

Naser Khalili

Position

Assistant of fellowship

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

Person responsible for updating data**Contact****Name of organization / entity**

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Position

Assistant of fellowship

Latest degree

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