

# 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

##### City

Tabriz

##### Province

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**

Naser Khalili

**Street address**

Univesity Main St

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

Tabriz University of Medical Sciences

**Full name of responsible person**

Mohammad Samiei

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Samiei.moh@gmail.com

**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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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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**Full name of responsible person**

Naser Aslan Abadi

**Position**

professor

**Latest degree**

Subspecialist

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**Full name of responsible person**

Naser Khalili

**Position**

Assistant of fellowship

**Latest degree**

Specialist

**Other areas of specialty/work**

Cardiology

**Street address**

Univesity Main St

**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