

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The Effect of prethrombolytic Cyclosporine A injection on Acute Anterior ST-Elevation Myocardial Infarction Outcome.

Protocol summary

Summary

Experimental evidence suggests that cyclosporine, which inhibits the opening of mitochondrial permeability-transition pores, attenuates myocardial reperfusion injury that occurs at the time of reperfusion. In this study, we are seeking to determine whether the administration of cyclosporine at the time of thrombolytic therapy reduces the rate of reperfusion injury during acute anterior STEMI. We will randomly assign 100 patients who will present with acute anterior ST-elevation myocardial infarction to receive either an intravenous bolus of 2.5 mg of cyclosporine per kilogram of body weight (cyclosporine group) or normal saline (control group) immediately before receiving thrombolytic therapy. First day and before discharge LVEF, signs and symptoms of Heart Failure, arrhythmia and in hospital and 6 months mortality will be assessed in all patients and compared between two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138807052474N2**

Registration date: **2010-01-09, 1388/10/19**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2010-01-09, 1388/10/19

Registrant information

Name

Mehdi Toluey Khormazard

Name of organization / entity

Tabriz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Research vice-chancellor of Tabriz University of Medical Sciences

Expected recruitment start date

2009-06-22, 1388/04/01

Expected recruitment end date

2010-04-21, 1389/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of prethrombolytic Cyclosporine A injection on Acute Anterior ST-Elevation Myocardial Infarction Outcome.

Public title

The Effect of prethrombolytic Cyclosporine A injection on Acute Anterior ST-Elevation Myocardial Infarction Outcome.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : in patients with 18 years of age or older, presence of ischemic chest pain and ST segment elevation of 1 mm or more in at least two contiguous leads of anterior region, who admits in primary six hours of symptoms onset and candidate for thrombolytic therapy Exclusion criteria : cardiac arrest, primary VF, prior MI, uncontrolled HTN, known hypersensitivity to

cyclosporine, known renal failure or a serum creatinine level of 120 mol per liter (1.36 mg per deciliter) or more at admission, liver failure, and women who were pregnant or who were of childbearing age and were not using contraception, any disorder that is associated with immunologic dysfunction e.g., cancer, lymphoma, a positive serologic test for the human immunodeficiency virus, or hepatitis

Age

From **20 years** old to **85 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Sciences, Daneshgah Ave.

City

Tabriz

Postal code**Approval date**

1387-12-05, 769/01/-835

Ethics committee reference number

5/4/10181

Health conditions studied**1****Description of health condition studied**

Acute myocardial infarction

ICD-10 code

I21.0

ICD-10 code description

Acute transmural myocardial infarction of anterior wall

Primary outcomes**1****Description**

LVEF

Timepoint

1st day & predischarge

Method of measurement

echocardiography

2**Description**

Incidence of Heart Failure

Timepoint

During admission

Method of measurement

Basal pulmonary rales , lasix using, chest XRAY

3**Description**

Incidence of Arrhythmia

Timepoint

During admission

Method of measurement

ECG monitoring

Secondary outcomes**1****Description**

All cause mortality rate

Timepoint

in hospital & 6 month later

Method of measurement

patient documents & calling

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

Cyclosporine 2.5 mg/kg in intervention group (pre thrombolytic)

Category

Treatment - Drugs

2**Description**

Normal saline in control group (pre thrombolytic)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Madani Heart Center

Full name of responsible person

Dr Mehdi Toluey Khormazard

Street address

Daneshgahe Ave.

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Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research vice-chancellor of Tabriz University of Medical Sciences

Full name of responsible person

Dr Rasool Azarafarin

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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

Research vice-chancellor of Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Dr Mehdi Toluey Khormazard

Position

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Other areas of specialty/work

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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