Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

Country

Iran (Islamic Republic of)

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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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Daneshgahe Ave.

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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
Resident of Cardiology

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Interventional cardiologist

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Person responsible for updating data

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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