

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 May 2026

Evaluation the effect of Trans Sodium Crocetinate(TSC) on re perfusion Injury in Acute Myocardial Infarction with ST elevation segment: a triple-blind, randomized, placebo-controlled trial

Protocol summary

Study aim

Investigating the oxygen-boosting effects of trans-sodium crocetinate and its properties in reducing the complications of reperfusion in acute myocardial infarction with ST-segment elevation.

Design

A randomized clinical trial, on 100 patients (two groups of 50 people), block randomization (via randomization site), parallel groups, triple-blind, phase 3.

Settings and conduct

The main medication, trans sodium crocetinate, is made in Mashhad School of Pharmacy in accordance with the principles of GLP, in addition to placebo, which is similar to the main medication in terms of vial shape and color. This study is performed in the heart ward of Imam Reza hospital in Mashhad.

Participants/Inclusion and exclusion criteria

Age between 18 and 76 years; myocardial infarction with an ascending ST segment; having AHA 2019 guideline criteria; candidates for PCI; zero TIMI score at admission.

Intervention groups

Intervention group: Patients under PPCI who receive TSC (trans sodium crocetinate) at a dose of 0.5 mg per body weight by injection within 2 minutes, 5 minutes before PCI, in addition to standard treatments for acute myocardial infarction, and then on days 0 to 3, patients receive 7.5 mg crocin tablets daily for 3 days. Control group: Patients under PCI who, in addition to standard treatments for acute myocardial infarction, receive a placebo vial that is injected within 2 minutes, 5 minutes before PCI, and then on days 0 to 3, Placebo tablets are taken 3 tablets a day for 3 days.

Main outcome variables

Quantitative amounts of troponin I(Tn I) enzyme

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120520009801N5**

Registration date: **2021-09-13, 1400/06/22**

Registration timing: **prospective**

Last update: **2021-09-13, 1400/06/22**

Update count: **0**

Registration date

2021-09-13, 1400/06/22

Registrant information

Name

Amir Hooshang Mohammadpour

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

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mohamadpoorah@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-09-23, 1400/07/01

Expected recruitment end date

2022-09-23, 1401/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of Trans Sodium Crocetininate(TSC) on re perfusion Injury in Acute Myocardial Infarction with ST elevation segment: a triple-blind, randomized, placebo-controlled trial

Public title

Evaluation the effect of Trans Sodium Crocetininate(TSC) on re perfusion Injury in Acute Myocardial Infarction

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients should be between 18 and 76 years old Patients with myocardial infarction with an ascending ST segment Meet the entry requirements under the AHA2019 guideline Candidates for PPCI Zero TIMI score at admission

Exclusion criteria:

Be pregnant or breastfeeding History of allergy to formulations used in the study. • The patient enters another similar plan and receives other drugs that affect treatment response in the past month The person has cardiogenic shock and is forced to use pressure therapy The patient has IABP History of acute myocardial infarction GFR less than 60 ml / min • Patients with cardiac arrest Patient with VF Patient with hepatic impairment AST / ALT > 5ULN Patient with a history of chronic inflammatory disease Patient with LMCA involvement Patient with a history of myocardial infarction or ACS within 4 hours before the current episode

Age

From **18 years** old to **76 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Alternate block randomization using www.randomization.com. Each block has 4 components and the mentioned site selects twenty-five blocks out of quadruple blocks randomly, so finally 100 patients are included in the study. The allocation concealment method is by use of opaque sealed envelopes with random sequences obtained from the random allocation step.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The vials will be marked with the letters A and B, and since the placebo will also be made by the Industrial Department of the School of Pharmacy, we will not have a problem with masquerade. It will be the same with pills. Physician, injecting drug nurse, clinical pharmacy resident, patients, and results analyzer will remain unaware of the type of formulation until completed.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mashhad University of Medical Sciences

Street address

Ethic committee of Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah stree

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Razavi Khorasan

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91375-345

Approval date

2021-08-11, 1400/05/20

Ethics committee reference number

IR.MUMS.REC.1400.131

Health conditions studied

1

Description of health condition studied

STEMI

ICD-10 code

I21.3

ICD-10 code description

ST elevation (STEMI) myocardial infarction of unspecified site

Primary outcomes

1

Description

Quantitative amounts of Troponin I Tn I enzyme and drawing the shape of the Tn I time concentration curve

Timepoint

At zero time, 6, 12 and 24 hours after PPCI

Method of measurement

High-Sensitivity Troponin Test-Laboratory

Secondary outcomes

1

Description

Evaluation of the patient's electrocardiogram and recording of ventricular and supraventricular arrhythmias, number of PVCs, PR / QT / QRS intervals, and evaluation of the cumulative amount of ST segment (STR Percentage)

Timepoint

Daily until discharge

Method of measurement

Through ECG examination

2

Description

Ejection fraction and evaluation of systolic and diastolic status of all 4 chambers of the heart and LV ENLARGMENT

Timepoint

Daily until discharge

Method of measurement

Echocardiography

3

Description

Evaluation of biochemical parameters INR, BUN, Scr Na, K, Ca, Mg, ALT, AST

Timepoint

Daily until discharge

Method of measurement

Laboratory

4

Description

Evaluation of the balance between oxidants - antioxidants

Timepoint

Two samples at time zero and patient discharge time

Method of measurement

Laboratory

Intervention groups

1

Description

Intervention group: Patients under PCI who receive trans sodium crocetinate""(TSC) at a dose of 0.5 mg / kg body weight by injection within 2 minutes, 5 minutes before PCI, in addition to standard treatments for acute myocardial infarction, then take crocetin oral tablets on days 0 to 3 At a dose of 7.5 mg, they take 3 tablets a day

Category

Prevention

2

Description

Control group: Patients under PCI receive normal saline at a dose of .05 mg/v in addition to standard treatments for acute myocardial infarction within 2 minutes, 5 minutes before PCI, and then 3 placebo tablets on days 0 to 3.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Raza hospital

Full name of responsible person

Amirhooshang Mohamadpoor

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Amir Hooshang Mohammadpour

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

all collected deidentified IPD

When the data will become available and for how long

starting 6 months after publication

To whom data/document is available

only available for people working in academic institutions

Under which criteria data/document could be used

only available for people working in academic institutions and there is not another condition

From where data/document is obtainable

mohamadpoorah@mums.ac.ir
What processes are involved for a request to access data/document

mohamadpoorah@mums.ac.ir
Comments