Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

A Randomized placebo controlled trial of Omega-3 on Plasma Level of Cardiac Troponin-I and Creatinine Kinase- MB in patients with myocardial infarctions who undergoing streptokinase therapy

Protocol summary

Summary

Objective: To evaluate the effect of omega-3 in myocardial infarction in patients undergoing streptokinase therapy. Design: A prospective, single blinded, randomized controlled trial on patients with myocardial infarction who undergoing streptokinase therapy. Setting and conduct: All patients with myocardial infarction who undergoing streptokinase therapy in Shahid Madani Hospital will be randomized (using permuted block randomization, block size 2, allocation ratio 1:1) in two groups of omega-3 treated (n=50) and control (n=50). Participants: All consented patients with myocardial infarction aged 18-80 who undergoing stereptokinase therapy. The exclusion criteria are elevation of CK-MB and cTnI at least 48 hours before injection of streptokinase; history of CABG during last three months; history of previous MI; renal dysfunction (creatinine above 2.5 mg/dl); contraindication of streptokinase injection; acute MI; cardiogenic shock; hypersensitivity to aspirin or clopidogrel or omega-3 and streptokinase injection. Intervention: In omega-3 group, all patients will be received totally 3 g oral omega-3 before streptokinase therapy. The control group will be received only standard treatment. Primary outcomes: Changes of CK-MB and cTnI level before, 8, and 24 hours after streptokinase injection in each groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201402078307N5**
Registration date: **2014-10-10, 1393/07/18**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-10-10, 1393/07/18

Registrant information

Name

Taher Entezari-Maleki

Name of organization / entity

Tehran University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2013-12-21, 1392/09/30

Expected recruitment end date

2014-06-20, 1393/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Randomized placebo controlled trial of Omega-3 on Plasma Level of Cardiac Troponin-I and Creatinine Kinase- MB in patients with myocardial infarctions who undergoing streptokinase therapy

Public title

Evaluation of omega-3 in reduction of myocardal damage

in patients with myocardial infarctions who undergoing streptokinase therapy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: myocardial infarction patients; age 18-80; undergoing of thrombolytic therapy with streptokinase; filling of consent form. Exclusion Criteria: Elevation of CK-MB and cTnI before injection of streptokinase; history of CABG during last three months; history of previous MI; renal dysfunction (creatinine above 2.5 mg/dl); contraindication of streptokinase therapy; acute MI; cardiogenic shock; Hypersensitivity to aspirin or clopidogrel or omega-3 and streptokinase injection.

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

-

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Committee on Medical Ethics of Tabriz University of Medical Sciences

Street address

Golgasht Street

City

Tabriz

Postal code

Approval date

2013-12-02, 1392/09/11

Ethics committee reference number

92143

Health conditions studied

1

Description of health condition studied

Myocardial Infarction

ICD-10 code

I23-I25.8

ICD-10 code description

Myocardial Infarction

Primary outcomes

1

Description

CK-MB level

Timepoint

Before, 8 and 24 hours after streptokinase injection

Method of measurement

ELISA kits

Secondary outcomes

1

Description

cTnI level

Timepoint

Before, 8 and 24 hours after streptokinase injection.

Method of measurement

ELISA kits

Intervention groups

1

Description

Intervention: in omega-3 group All patients will be received 3 grams of omega-3 before streptokinase injection.

Category

Treatment - Drugs

2

Description

Control: In the control group, patients only will be given the standard treatment.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Madani Heart Center of Tabriz

Full name of responsible person

Dr. Taher Entezari-Maleki

Street address
Shahid Madani Heart Center, Daneshghah Street
City
tabriz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research of Tabriz University of Medical Sciences.
Full name of responsible person
Dr. Mohammad Reza Rashidi
Street address
Daneshghah street
City
tabriz
Grant name
-
Grant code / Reference number
-
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research 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

Person responsible for scientific inquiries

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Name of organization / entity
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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