Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jun 2026

comparison of efficacy and safety of high-dose versus low-dose aspirin in patients with ST-segment myocardial infarction (STEMI) after primary percutaneous coronary intervention

Protocol summary

Summary

objective: The aim of this study is to compare long term safety and efficacy of low-dose versus high-dose aspirin in patients with ST segment elevation myocardial infarction (STEMI)undergoing primary percutaneous coronary intervention (PCI). design: This is a double-blind parallel randomized clinical trial. setting and conduct: this study perform at Heshmat hospital, Rasht, Iran. participants: patients with STEMI defined as typical chest pain lasting for >30 minutes and ST-segment elevation >1 mm in >2 contiguous electrocardiographic leads, who underwent primary PCI within 12 hours of the onset of symptoms include to the study. Patients with a history of gastrointestinal bleeding and hemorrhagic stroke exclude from the study. An informed consent will be provided for all patients to participate. intervention: Eligible patients then randomly allocate to receive 325 mg daily as high-dose aspirin or 81 mg daily as low-dose aspirin for one month. Drugs will be provided in similar boxes labeled as A or B. main outcome variables: death, myocardial infarction, revascularization procedure stroke and major bleeding during one year after primary PCI.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014122220392N1**
Registration date: **2016-02-28, 1394/12/09**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-02-28, 1394/12/09

Registrant information

Name

Fatemeh Moaddab

Name of organization / entity

Guilan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Guilan University of Medical Sciences. Address: vice chancellor for research building, west Shahid Beheshti highway, Rasht, Iran

Expected recruitment start date

2013-03-21, 1392/01/01

Expected recruitment end date

2014-03-21, 1393/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison of efficacy and safety of high-dose versus low-dose aspirin in patients with ST-segment myocardial infarction (STEMI) after primary percutaneous coronary intervention

Public title

efficacy and safety of various aspirin doses in patients with ST-segment myocardial infarction undergoing primary percutaneous coronary intervention

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: patients with ST-segment myocardial infarction who underwent primary PCI within 12 hours of the onset of heart attack. Exclusion Criteria:patients with a history of gastrointestinal bleeding and hemorrhagic stroke; opium and alcohol abusers, patients with coagulopathies or history of anticoagulant therapy ; major surgery within 6 weeks; platelets less than 100,000/ microliter; hematocrit less than 25%; creatinine more than 4 mg/dl

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **175**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee, Guilan University of Medical Sciences

Street address

Vice chancellor for research building, West Shahid Beheshti highway, Rasht, Iran

City

Rasht

Postal code

Approval date

2013-07-29, 1392/05/07

Ethics committee reference number

1920141901

Health conditions studied

1

Description of health condition studied

ST-segment elevation myocardial infarction (STEMI)

ICD-10 code

I21

ICD-10 code description

Acute myocardial infarction

Primary outcomes

1

Description

Major adverse cardiovascular outcome

Timepoint

one month and one year after the study

Method of measurement

telephone interview and echcardiogarphy for patients with primary outcome

Secondary outcomes

1

Description

Major bleeding

Timepoint

one month and one year after primary PCI

Method of measurement

telephone interview

Intervention groups

1

Description

The intervention group receive aspirin with chemical substance of acetyl salisilic acid as 325 mg orally tablet once a day for a duration of 1 month from days 2-30 after primary PCI.

Category

Treatment - Drugs

2

Description

The control group receive aspirin with chemical substance of acetyl salisilic acid as 80 mg orally tablet once a day for a duration of 1 month from days 2-30 after primary PCI.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Heshmat Hospital

Full name of responsible person

Dr. Pursadeghi

Street address

Heshmat Hospital, 15 khordad street, Rasht

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Guilan University of Medical Sciences

Full name of responsible person

Dr. Rasoul Tabari

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vice chancellor for research building, west Shahid Beheshti highway, Rasht, Iran

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Rasht

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, Guilan 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

Guilan university of medical sciences

Full name of responsible person

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Position

Resident of Cardiology

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