

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Comparing the effect of Loading Doses of Clopidogrel and Prasugrel on the incidence of myocardial injury in the Candidates for Elective Percutaneous Coronary Intervention

Protocol summary

Summary

Prevention of myocardial injury is an essential issue in percutaneous coronary intervention (PCI). We aim to compare the incidence of myocardial injury after loading doses of clopidogrel versus prasugrel in the candidates for elective PCI. In this randomized-controlled clinical trial, we enrol 90 patients with stable angina who are candidates for elective PCI. Patients will be dedicated into 2 groups to receive either Prasugrel (60 mg P.O. stat) or Plavix (600 mg P.O. stat). Serum levels of CK-MB, cardiac troponin I (cTnI) and high sensitive C - reactive protein (hs-CRP) will be measured at baseline and 6 and 12 hours post-procedural. Primary endpoint are periprocedural MI, defined as elevation of cTn values (>5 times) in patients with normal baseline values or a rise of cTn values >20% if the baseline values are elevated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201408069768N3**

Registration date: **2014-08-19, 1393/05/28**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-08-19, 1393/05/28

Registrant information

Name

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Name of organization / entity

Tehran Heart Center, Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2013-01-01, 1391/10/12

Expected recruitment end date

2014-01-01, 1392/10/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of Loading Doses of Clopidogrel and Prasugrel on the incidence of myocardial injury in the Candidates for Elective Percutaneous Coronary Intervention

Public title

Comparing the effect of Loading Doses of Clopidogrel and Prasugrel on the incidence of myocardial injury in the Candidates for Elective Percutaneous Coronary Intervention

Purpose

Treatment

Inclusion/Exclusion criteria

we enrolled patients with stable angina who were candidate for elective PCI and gave informed consent to take part in this trial. The exclusion criteria included: history of coronary artery bypass graft surgery; need for

emergency PCI (in less than 2 hours); history of renal dysfunction; any contraindication for prasugrel or Plavix; body weight < 60 kg; age ≥ 75 years; history of cerebrovascular accident and transient ischemic attack, serum creatinine > 1.5 mg/dl; and ejection fraction < 30%.

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **90**

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

Imam Khomeini Hospital

Street address

Keshavarz Blvd, Dr. Gharib st

City

Tehran

Postal code

Approval date

2011-11-20, 1390/08/29

Ethics committee reference number

4912-90-10

Health conditions studied

1

Description of health condition studied

Subsequent myocardial infarction

ICD-10 code

I22

ICD-10 code description

For morbidity coding, this category should be assigned for infarction of any myocardial site, occurring within 4 weeks (28 days) from onset of a previous infarction

Primary outcomes

1

Description

periprocedural myocardial infarction

Timepoint

elevation of cTn values (>5 times) in patients with normal baseline values or a rise of cTn values >20% if the baseline values are elevated

Method of measurement

Blood survey

Secondary outcomes

empty

Intervention groups

1

Description

Prasugrel (60 mg P.O. stat)

Category

Treatment - Drugs

2

Description

Plavix (600 mg P.O. stat)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

imam Khomeini Hospital

Full name of responsible person

Reza Rahmani

Street address

Keshavarz Blvd, Dr. Gharib st

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Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Reza Rahmani

Street address

Keshavarz blvd, dr Gharib st

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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

Tehran 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

Tehran Heart Center

Full name of responsible person

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Md, MSc

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