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 90patients with stable angina who arecandidate for elective PCI. Patients will be dedicated into 2 groups te 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

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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>1.5mg/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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Reza Rahmani

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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

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Person responsible for updating data

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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