

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Evaluation of N-acetyl cystein on myocardial perfusion and plasma troponin I and hsCPR levels in patients undergoing primary PCI

Protocol summary

Summary

We designed this study to evaluate the effect of N-acetylcystein on biomarkers of coronary reperfusion and Troponin I as well as high sensitive C-Reactive Protein (hs-CRP) in patients undergoing percutaneous coronary intervention. Double blind randomized clinical trial on 100 patients in 2 groups (intervention & control) are selected. Patients with ST-segment elevated myocardial infarction included. Patients were excluded if had: emergency for cardiac bypass ,cardiogenic shock or underwent rescue percutaneous coronary intervention . The patients in Intervention group were administered to take 100 mg/kg IV bolus N-acetylcystein and then intracoronary and 10mg/kg/h over 12 hours after percutaneous coronary intervention and patients in control group received standard regimens. Primary outcomes were Troponin I and hs-CRP measured before and 48 hours after percutaneous coronary intervention. Patients were assessed for coronary blood flow after percutaneous coronary intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201301048698N8**
Registration date: **2013-01-19, 1391/10/30**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-01-19, 1391/10/30

Registrant information

Name

Azita Hajhossein Talasaz

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Tehran Heart Center, Tehran University of Medical Sciences

Expected recruitment start date

2012-02-01, 1390/11/12

Expected recruitment end date

2013-02-01, 1391/11/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of N-acetyl cystein on myocardial perfusion and plasma troponin I and hsCPR levels in patients undergoing primary PCI

Public title

NAC effects on patients with AMI undergoing angioplasty

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria: Myocardial infarction patients who were candidate of primary PCI . Exclusion Criteria: rescue pci; emergency for cardiac bypass ; cardiogenic shock; life expectancy less than 6 months; Age less than 18 years old; Uncontrolled hypertension; Thrombocytopenia; Malformation or aneurysm; severe chronic renal failure;

Sever liver failure; treatment with glycoprotein IIb/IIIa inhibitors during PCI ; sensitivity to sulfonamides ; Major surgery; Unsatisfactory to enter to study

Age

From **18 years** old to **90 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran Heart Center

Street address

Jalal Ale Ahmad, North Karegar

City

Tehran

Postal code

Approval date

2012-08-13, 1391/05/23

Ethics committee reference number

586

Health conditions studied

1

Description of health condition studied

Myocardial Infarction

ICD-10 code

I21

ICD-10 code description

Acute Myocardial Infarction

Primary outcomes

1

Description

Troponin I

Timepoint

Baseline and after 48 hours

Method of measurement

Elisa Kit

2

Description

hs-CRP

Timepoint

Baseline and after 48 hours

Method of measurement

Elisa Kit

3

Description

Myocardial Perfusion

Timepoint

Baseline and after Primary Percutaneous Coronary Intervention

Method of measurement

Myocardial Blush Grage and TIMI flow

Secondary outcomes

empty

Intervention groups

1

Description

Intervention: The patients in Intervention group were adminitered to take 100 mg/kg IV bolus N-acetylcystein and then intracoronary and 10mg/kg/h over 12 hours after percutaneous coronary intervention

Category

Prevention

2

Description

Control: Received Standard treatment as for patients with acute myocardial infarction

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran Heart Center

Full name of responsible person

Azita Hajhossein Talasaz

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North Kargar St., Jalal Al Ahmand St.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran Heart Center, Tehran University of Medical Sciences

Full name of responsible person

Somayeh Kalaiee

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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 Heart Center, 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

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Full name of responsible person

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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