

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Evaluation of N-acetylcystein on biomarkers of platelet activation and coronary reperfusion in patients undergoing percutaneous coronary intervention

Protocol summary

Summary

We designed this study to evaluate the effect of N-acetylcystein on biomarkers of platelet activation and coronary reperfusion in patients undergoing percutaneous coronary intervention. Double blind randomized clinical trial on 100 patients in 2 groups (intervention & control) are selected. Patients have Myocardial infarction included. Patients were excluded if had: emergency for cardiac bypass ,cardiogenic shock , treatment with glycoprotein IIb/IIIa inhibitors during percutaneous coronary intervention and 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 outcome was platelet activation biomarkers assessment before and 24 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: **IRCT201210118698N2**
Registration date: **2012-11-02, 1391/08/12**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-11-02, 1391/08/12

Registrant information

Name

Azita Hajhossein Talasaz

Name of organization / entity

Department of Clinical Pharmacy, Faculty of Pharmacy, Tehran University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2011-01-21, 1389/11/01

Expected recruitment end date

2012-11-21, 1391/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of N-acetylcystein on biomarkers of platelet activation and coronary reperfusion in patients undergoing percutaneous coronary intervention

Public title

Effect of N-acetylcystein in myocardial infarction

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; sever 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)

Double 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

North karegar-jalaaal alle ahmad avenue

City

tehran

Postal code

1411713138

Approval date

2011-12-13, 1390/09/22

Ethics committee reference number

268

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

IL-10 biomarker of stenosis

Timepoint

after intervention

Method of measurement

Serum concentration ng/ml

2

Description

TGF- β biomarker of stenosis

Timepoint

after intervention

Method of measurement

serum concentration ng/ml

3

Description

CD40L biomarker of restenosis

Timepoint

after intervention

Method of measurement

serum concentration ng/ml

4

Description

P-selectin biomarker of restenosis

Timepoint

After intervention

Method of measurement

serum concentration ng/ml

Secondary outcomes

1

Description

TIMI a score of coronary blood flow

Timepoint

after intervention

Method of measurement

number

2

Description

MBG a score of coronary blood flow

Timepoint

after intervention

Method of measurement

number

3

Description

MACE

Timepoint

30-daye after intervention
Method of measurement
observation

4

Description
Added at 2014-08-03: Major Adverse cardiac events
Timepoint
Added at 2014-08-03: 30 days and 2 years
Method of measurement
Added at 2014-08-03: call to patient

Intervention groups

1

Description
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
Category
Treatment - Drugs

2

Description
Standard regimen for Primary percutaneous coronary intervention (Heparin,Clopidogrel ,ASA)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Tehran heart center
Full name of responsible person
Dr.Talaasaz
Street address
North karegar-jalaal ale ahmad avenue
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mr. Jafari
Street address
Tehran University of Medical Sciences
City
tehran
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, Shaheed Beheshti University of Medical Sciences

Full name of responsible person
Azita Hajhossein Talasaz, Jamshid Salamzadeh

Position
Assistant professor, Associated professor

Other areas of specialty/work

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Person responsible for scientific inquiries

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Full name of responsible person
Azita Hajhossein Talasaz, Jamshid Salamzadeh

Position
assistant, associated

Other areas of specialty/work

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Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Shaheed Beheshti University of Medical Sciences

Full name of responsible person

Azadeh Eshraghi

Position

Resident of clinical pharmacy

Other areas of specialty/work**Street address**

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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