Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation the effects of N Acetyl Cysteine (NAC) in myocardial reperfusion of patients with STEMI undergoing to P-PCI in Karaj's Shahid Rajayi hospital in 2020

Protocol summary

Study aim
The effects of N Acetyl Cysteine in myocardial reperfusion of patients with STEMI undergoing P-PCI will be evaluated to reduce slow flow in angiography.

Design
Two arms parallel-group double-blinded randomized trial with a control group, phase 3 on 142 patients. Rand function on excel software for block randomization was used.

Settings and conduct
Catheterization Laboratory Angiography Operation Room in Shahid Rajaii Hospital

Participants/Inclusion and exclusion criteria
Patients with STEMI candidate for primary PCI who not having renal failure, allergy to N Acetyl Cysteine, and asthma included.

Intervention groups
1200mg N Acetyl Cysteine before primary PCI and every 12 hours for 2 days will be injected intravenously for the intervention group. For the control group serum dextrose 5% as a placebo will be used.

Main outcome variables
Troponin I; CK-MB; TIMI Flow Grade; Corrected TIMI Frame Count; Left Ventricle Ejection Fraction; Left Ventricle End Diastolic Volume; Left Ventricle End Systolic Volume

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200519047506N1**
Registration date: **2020-09-18, 1399/06/28**
Registration timing: **registered_while_recruiting**

Last update: **2020-09-18, 1399/06/28**
Update count: **0**

Registration date
2020-09-18, 1399/06/28

Registrant information

Name
Huma Arabi

Name of organization / entity
Alborz University of Medical Science

Country
Iran (Islamic Republic of)

Phone
+98 21 4446 0486

Email address
miss.arabi@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-07-22, 1399/05/01

Expected recruitment end date
2020-09-22, 1399/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation the effects of N Acetyl Cysteine (NAC) in myocardial reperfusion of patients with STEMI undergoing to P-PCI in Karaj's Shahid Rajayi hospital in 2020

Public title
Evaluation the effect of N Acetyl Cystein (NAC) in myocardial infarction

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients admitted at Shahid Rajaii hospital in karaj in 2020 Patients admitted with myocardial infarction Patients who had STEMI Patients candidate for Primary PCI
Exclusion criteria:
Patients who have renal failure Patients who have allergy to N Acetyl Cystein Patients who have asthma
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **142**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization with a block size of 4 patients which every single block contains the equal groups. There was 6 possible way for randomization in a block. We randomly choose blocks, so the total on A and the total on B only differed by a maximum of 2. So say the first Block is AABB and the total subjects on A and B will be; (1,0), (2,0), (2,1), (2,2)
Blinding (investigator's opinion)
Double blinded
Blinding description
Interventionist and the researcher who analyzes data both use patient's code. Also, title groups were coded with A and B whom none of them know which one is the NAC or control group.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Alborz University of Medical Science
Street address
Shahid Rajaii Hospital, Rajaii Ave, Shahid Beheshti Blvd, Karaj Town, Alborz
City
Karaj
Province
Alborz
Postal code
3197635141
Approval date
2020-08-24, 1399/06/03
Ethics committee reference number
IR.ABZUMS.REC.1399.130

Health conditions studied

1

Description of health condition studied
Acute myocardial infarction
ICD-10 code
I21
ICD-10 code description
ST elevation (STEMI) and non-ST elevation (NSTEMI) myocardial infarction

Primary outcomes

1

Description
Troponin level
Timepoint
Prior to intervention, 24 hour and 48 hour after intervention
Method of measurement
Blood test

2

Description
Creatine kinase MB level
Timepoint
Prior to intervention and 24 hour and 48 hour after intervention
Method of measurement
Blood test

3

Description
Blood Urea
Timepoint
Prior to intervention and 24 hour after intervention
Method of measurement
Blood test

4

Description
Ejection Fraction
Timepoint
After intervention and 1 month after discharge
Method of measurement

Echocardiography

5

Description
Left ventricle end systolic volume
Timepoint
After intervention and 1 month after discharge
Method of measurement
Echocardiography

6

Description
Left ventricle end diastolic volume
Timepoint
After intervention and 1 month after discharge
Method of measurement
Echocardiography

7

Description
Blood creatinine
Timepoint
Prior to intervention and 24 hour after intervention
Method of measurement
Blood test

8

Description
Thrombolysis in myocardial infarction
Timepoint
Prior to and after intervention
Method of measurement
Angiography

9

Description
Corrected thrombolysis in myocardial infarction frame count
Timepoint
After intervention
Method of measurement
Angiography

Secondary outcomes

1

Description
Mortality
Timepoint
After 6 month
Method of measurement
Asking by telephone call

Intervention groups

1

Description
Intervention group: 1200 mg N Acetyl Cysteine prior to primary PCI and every 12 hour for 48 hour will be injected intravenously.
Category
Treatment - Drugs

2

Description
Control group: 100 cc serum dextrose 5% prior to primary PCI and every 12 hour for 48 hour will be injected intravenously.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Rajaii hospital
Full name of responsible person
Huma Arabi
Street address
Shahid Rajaii hospital, Rajaii St, Shahid beheshti Ave, Hesarak Sq
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Karaj University of Medical Sciences
Full name of responsible person
Dr Mohammad Noori Sepehr
Street address
Vice Chancellery for Research and Technology, Saffarian Street, Golshahr Ave, Karaj
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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
Karaj University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Alborz University of Medical Science
Full name of responsible person
Huma Arabi
Position
Medical student
Latest degree
A Level or less
Other areas of specialty/work
General Practitioner
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No 94, West Khodadoost Street, First Southern Street, Mokhberi Avenue, Central Jannat Abad Avenue, Tehran, Iran
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Person responsible for scientific inquiries

Contact

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Position
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Other areas of specialty/work
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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

The study protocol, informed consent, study result, and some parts of IPD will be shared.

When the data will become available and for how long

6 month after result edition

To whom data/document is available

Everybody

Under which criteria data/document could be used

No condition needed.

From where data/document is obtainable

Huma Arabi miss.arabi@yahoo.com

What processes are involved for a request to access data/document

After sending email and obtaining identity data information will be accessible in 2 weeks.

Comments