

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 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

#### **City**

Karaj

#### **Province**

Alborz

#### **Postal code**

3197635141

#### **Phone**

+98 26 3457 0030

#### **Fax**

#### **Email**

miss.arabi@yahoo.com

#### **Web page address**

<https://rajaei.abzums.ac.ir/fa-IR/rajaei.abzums.ac/6132/page/%D8%B5%D9%81%D8%AD%D9%87-%D8%A7%D8%B5%D9%84%DB%8C>

## **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

#### **City**

Karaj

#### **Province**

Alborz

**Postal code**

3198764653

**Phone**

+98 26 3464 3774

**Fax****Email**

Research@abzums.ac.ir

**Web page address**

https://research.abzums.ac.ir/fa-IR/research.abzums.a  
c/9132/page/%D8%B5%D9%81%D8%AD%D9%87-  
%D8%A7%D8%B5%D9%84%DB%8C-  
%D9%85%D8%B9%D8%A7%D9%88%D9%86%D8%A  
A

**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

**Street address**

No 94, West Khodadoost Street, First Southern Street,  
Mokhberi Avenue, Central Jannat Abad Avenue,  
Tehran, Iran

**City**

Karaj

**Province**

Alborz

**Postal code**

1475673444

**Phone**

+98 21 4446 0486

**Fax****Email**

miss.arabi@yahoo.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Alborz University of Medical Science

**Full name of responsible person**

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available	some parts of IPD will be shared.
<b>Study Protocol</b>	<b>When the data will become available and for how long</b>
Yes - There is a plan to make this available	6 month after result edition
<b>Statistical Analysis Plan</b>	<b>To whom data/document is available</b>
No - There is not a plan to make this available	Everybody
<b>Informed Consent Form</b>	<b>Under which criteria data/document could be used</b>
Yes - There is a plan to make this available	No condition needed.
<b>Clinical Study Report</b>	<b>From where data/document is obtainable</b>
Yes - There is a plan to make this available	Huma Arabi miss.arabi@yahoo.com
<b>Analytic Code</b>	<b>What processes are involved for a request to access data/document</b>
No - There is not a plan to make this available	After sending email and obtaining identity data information will be accessible in 2 weeks.
<b>Data Dictionary</b>	<b>Comments</b>
No - There is not a plan to make this available	
<b>Title and more details about the data/document</b>	
The study protocol, informed consent, study result, and	