

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Determining the mechanism of N-acetylcysteine in the prevention of early remodeling, role of oxidative stress

Protocol summary

Summary

The main objective of this study was to determine the mechanism of N-acetylcysteine in the prevention of cardiac remodeling secondary to ischemia and acute myocardial infarction. In 80 patients with diagnosis of acute myocardial infarction who were assigned into two groups (40 each) to receive NAC 600 mg BD or placebo with the same dose for 3 days, the level of tumor necrosis factor-alpha and transforming growth factor-beta will be measured after 24 and 72 hours. The results will be compared in these two groups to determine if oxidative stress plays a role in NAC effect on the prevention of early cardiac remodeling.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201102283449N5**
Registration date: **2011-08-01, 1390/05/10**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-08-01, 1390/05/10

Registrant information

Name

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Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2010-08-01, 1389/05/10

Expected recruitment end date

2011-08-01, 1390/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determining the mechanism of N-acetylcysteine in the prevention of early remodeling, role of oxidative stress

Public title

Determining NAC mechanism in the prevention of early remodeling

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria; Patients with criteria of first episode of ST-elevation AMI including typical chest pain with the duration of more than 30 minutes, >1-mm ST elevation in ≥ 2 adjacent limb leads or >2-mm ST elevation in ≥ 2 adjacent chest leads, and a raise in creatine kinase or in troponin T level 2 times the upper limit of normal were included in the study. Exclusion Criteria; Patients with history of prior AMI, heart failure, atrial fibrillation, valvular dysfunction, and neoplastic, renal, liver, or thyroid diseases were excluded from the study. Moreover patients with current acute or chronic infections, autoimmune diseases, surgical procedures in the past 3 months; under treatment with anti-inflammatory drugs, supplements and antioxidants, subsequent MI, discharge or death during the study period were excluded.

Age	24 and 72 hours after administration of NAC or Placebo
No age limit	
Gender	Method of measurement
Both	Elisa
Phase	2
N/A	Description
Groups that have been masked	Transforming growth factor-beta
No information	Timepoint
Sample size	24 and 72 hours after administration of NAC or Placebo
Target sample size: 80	Method of measurement
Randomization (investigator's opinion)	Elisa
Randomized	
Randomization description	Secondary outcomes
Blinding (investigator's opinion)	empty
Double blinded	
Blinding description	Intervention groups
Placebo	
Used	1
Assignment	Description
Parallel	Intervention: NAC 600 mg BD for 3 days per oral
Other design features	Category
	Prevention
Secondary Ids	2
empty	Description
	Control: Placebo BD for 3 days per oral
Ethics committees	Category
	Prevention
1	
Ethics committee	Recruitment centers
Name of ethics committee	1
Tehran University of Medical Sciences	Recruitment center
Street address	Name of recruitment center
Tehtan University of Medical Sciences, Enghelab Ave	Tehran Heart Center
City	Full name of responsible person
Tehran	Street address
Postal code	City
	Tehran
Approval date	
2011-07-23, 1390/05/01	Sponsors / Funding sources
Ethics committee reference number	1
90-2-33-13830	Sponsor
Health conditions studied	Name of organization / entity
	Tehran University of Medical Sciences
1	Full name of responsible person
Description of health condition studied	Fatemeh Saieedi
Acute Myocardial Infarction	Street address
ICD-10 code	Tehran University of Medical Sciences, Enghelab Ave
I21	City
ICD-10 code description	Tehran
Acute Myocardial Infarction	Grant name
Primary outcomes	Grant code / Reference number
	Is the source of funding the same sponsor organization/entity?
1	
Description	
Tumor necrosis factor-alpha	
Timepoint	

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

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences
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