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 mechamism 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
Hossein Khalili

Name of organization / entity
Tehran University of Medical Sciences

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Iran (Islamic Republic of)

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khalilih@tums.ac.ir

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
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tehran University of Medical Sciences
Street address
Tehtan University of Medical Sciences, Enghelab Ave
City
Tehran
Postal code
Approval date
2011-07-23, 1390/05/01
Ethics committee reference number
90-2-33-13830

Health conditions studied

1

Description of health condition studied
Acute Myocardial Infarction
ICD-10 code
I21
ICD-10 code description
Acute Myocardial Infarction

Primary outcomes

1

Description
Tumor necrosis factor-alpha
Timepoint
24 and 72 hours after administration of NAC or Placebo
Method of measurement
Elisa

2

Description
Transforming growth factor-beta
Timepoint
24 and 72 hours after administration of NAC or Placebo
Method of measurement
Elisa

Secondary outcomes

empty

Intervention groups

1

Description
Intervention: NAC 600 mg BD for 3 days per oral
Category
Prevention

2

Description
Control: Placebo BD for 3 days per oral
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Tehran Heart Center
Full name of responsible person
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Fatemeh Saieedi
Street address
Tehran University of Medical Sciences, Enghelab Ave
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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Hossein Khalili

Position

Associate Professor

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

Azita Hajhossein Talasaz

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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