Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Protection rule of N-acetyl L-cysteine in improvement of pulmonary condition in chronic obstructive pulmonary disease (COPD) patients after coronary artery bypass grafting (CABG) surgery

Protocol summary

Summary

In previous studies, during acute attack of COPD level of oxidants increases in human body and natural anti-oxidants are not able to neutralization them.Inclusion criteria:Age 25 to 60 years old;Ejection fraction more than or equal to 40 percent Exclusion criteria :Massive blood transfusion; Any complication caused prolongation of operation or intubation. During open heart surgery, pulmonary-heart pump decreases anti-oxidants level and increases oxidants. The COPD patients who are undergoing to open heart surgery, after surgery more pulmonary complications occur than the patients without pulmonary problem. N-acetyl cysteine (NAC) is an antioxidant that in this study as prevention effects of heart-pulmonary pump are studied.Ṡixty patients were randomly divided in random fix block method into two groups of 1 and 2 . The first group received 9 doses of NAC 200mg NAC during operation and second group received placebo (Normal saline) at the same time and in the same dose. Patients will be followed for 30 days after surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201509064345N5**
Registration date: **2015-10-04, 1394/07/12**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2015-10-04, 1394/07/12

Registrant information

Name

Ali Mirmansouri

Name of organization / entity

Guilan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Guilan university of medical sciences

Expected recruitment start date

2015-10-07, 1394/07/15

Expected recruitment end date

2016-03-05, 1394/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Protection rule of N-acetyl L-cysteine in improvement of pulmonary condition in chronic obstructive pulmonary disease (COPD) patients after coronary artery bypass grafting (CABG) surgery

Public title

The effect of N-acetyl L-cysteine in Chronic obstructive pulmonary disease

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:Age 25 to 60 years old;Ejection fraction more than or equal to 40 percent Exclusion criteria

:Massive blood transfusion; Any complication caused prolongation of operation or intubation

Age
From **25 years** old to **60 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **60**

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
Ethics committee of Guilan University of Medical Sciences

Street address
Shahid Beheshti Freeway

City
Rasht

Postal code
4193893345

Approval date
2015-08-24, 1394/06/02

Ethics committee reference number
IR.GUMS.REC.1394.201

Health conditions studied

1

Description of health condition studied
Chronic obstructive pulmonary disease

ICD-10 code
J44

ICD-10 code description
Other chronic obstructive pulmonary disease

Primary outcomes

1

Description
PULMONARY FUNCTION

Timepoint
Before surgery,5,15,30 days after surgery

Method of measurement
PULMONARY FUNCTION TEST(PFT)/With spirometery/Bionet SPM 300/ south Korea

2

Description
Arterial blood gas (ABG)

Timepoint
Before and after surgery then every 4 hours in ICU

Method of measurement
blood from an artery intraarterial cannula/convergent

Secondary outcomes

empty

Intervention groups

1

Description
Intervention1: In group N-acetylcysteine, before surgery, injected the first dose of 200 mg per mL of N-acetyl L-cysteine / EXIR Co./IRAN

Category
Treatment - Drugs

2

Description
placebo group: Similar to intervention 1 classification, but we used placebo (NS intravenously instead of NAC)

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Heshmat Hospital

Full name of responsible person
Ali Mirmansouri

Street address
Fifteenth Khordad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Guilan University of Medical Sciences

Full name of responsible person
Abtin Heidarzadeh

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Shahid Beheshti Freeway

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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
Vice chancellor for research of Guilan 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
Guilan University of Medical Sciences

Full name of responsible person
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Position
Anesthesiologist

Other areas of specialty/work

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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