

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. Sixty 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

Country

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 spirometry/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

City

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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

Street address

Shahid Beheshti Freeway

City

Rasht

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

Ali Mirmansouri

Position

Anesthesiologist

Other areas of specialty/work

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Full name of responsible person

Hedyeh Nemati

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Medical laboratory Sciences Technician/ Bachelor's Degree

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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