

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Investigation of the effect of N-acetyl cysteine on liver function after open heart surgery

Protocol summary

Study aim

The effect of N-acetyl cysteine on the prevention of hepatic ischemia after open heart surgery

Design

In this study, 60 patients with blind double-sided blind clinical trial were randomly divided into two groups of intervention and control.

Settings and conduct

In this study, 60 patients who are candidates for open heart surgery in Golestan Hospital of Ahvaz will be selected as available and will be divided into two groups of intervention and control in a simple random manner. They will receive mg/kg of N-acetyl cysteine. In the control group, after induction of anesthesia and intubation, 150 mg / kg normal saline will be given intravenously. In order to conduct a two-way blind study of patients and researchers who inject the drug and take a blood sample from They don't know which medicine or which drug.

Participants/Inclusion and exclusion criteria

Criteria for admission: Open heart surgery; age 30 to 70 years; normal kidney and liver function; no diabetes, hypertension, thyroid dysfunction and cardiac arrhythmia; no addiction

Intervention groups

In the intervention group, after induction of anesthesia and intubation, 150 mg / kg N-acetylcysteine will be administered intravenously. In the control group, after induction of anesthesia and intubation, 150 mg / kg normal saline will be administered intravenously.

Main outcome variables

Patients who entered the study would be screened for serum Alkaline Phosphatase, Aspartate Aminotransferase, alanine, Alanine Aminotransferase, Gamma Glutamyl Transferase, and Bilirubin in a blood test after open heart surgery.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190506043492N2**

Registration date: **2020-05-23, 1399/03/03**

Registration timing: **retrospective**

Last update: **2020-05-23, 1399/03/03**

Update count: **0**

Registration date

2020-05-23, 1399/03/03

Registrant information

Name

Milad Arabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3374 3001

Email address

arabi.m@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-21, 1397/02/01

Expected recruitment end date

2020-01-05, 1398/10/15

Actual recruitment start date

2018-09-11, 1397/06/20

Actual recruitment end date

2020-01-10, 1398/10/20

Trial completion date

2020-01-10, 1398/10/20

Scientific title

Investigation of the effect of N-acetyl cysteine on liver function after open heart surgery

Public title

the effect of N-acetyl cysteine on liver function after open heart surgery

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

Entry Criteria: Candidates for open heart surgery Be 30 to 70 years old Have normal kidney and liver function Do not have thyroid disease, hypertension, diabetes and arrhythmia Don't be addicted to drugs.

Exclusion criteria:

Output criterion: The patient is not satisfied to participate in the study If the patient is taking effective drugs such as steroids, anti-inflammatory or anti fungal drugs If you are allergic to N-acetyl cysteine

Age

From **30 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were randomly selected and divided into two groups of interventions (recipient of N-acetyl cysteine) and control (normal recipient of saline) through a table of random numbers assigned to even numbers for the intervention group and individual numbers for the control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, patients were unaware that they were in the receiving group of N-acetyl cysteine or normal saline, The person injecting the drug did not know if the syringe contained N-acetyl cysteine or normal saline, Because the drug was taken by another anesthesiologist and labeled 1 and 2, and Finally, the person who took the blood sample from the patients for liver tests did not know the type of intervention and the type of medicine that had been injected for the patients.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of ahvaz jundishapur University of Medical Sciences

Street address

Ground Floor, Central Library, Ahvaz Jundishapur University of Medical Sciences, Golestan BLvd., Ahvaz

City

Ahvaz

Province

Khuzestan

Postal code

61357157941

Approval date

2019-08-19, 1398/05/28

Ethics committee reference number

IR.AJUMS.REC.1398.391

Health conditions studied**1****Description of health condition studied**

Liver diseases

ICD-10 code

K76.9

ICD-10 code description

Liver disease, unspecified

Primary outcomes**1****Description**

The effect of N-acetyl cysteine on liver enzymes after open heart surgery

Timepoint

Before anesthesia, 1, 24 and 48 hours later

Method of measurement

Serum levels of alkaline phosphatase in blood tests

2**Description**

The effect of N-acetyl cysteine on liver enzymes after open heart surgery

Timepoint

Before anesthesia, 1, 24 and 48 hours later

Method of measurement

Serum levels of Aspartate Aminotransferase Alanine in blood tests

3

Description

The effect of N-acetyl cysteine on liver enzymes after open heart surgery

Timepoint

Before anesthesia, 1, 24 and 48 hours later

Method of measurement

Serum levels of Aminotransferase in blood tests

4

Description

The effect of N-acetyl cysteine on liver enzymes after open heart surgery

Timepoint

Before anesthesia, 1, 24 and 48 hours later

Method of measurement

Serum levels of Gamma Glutamyl Transferase in blood tests

5

Description

The effect of N-acetyl cysteine on liver enzymes after open heart surgery

Timepoint

Before anesthesia, 1, 24 and 48 hours later

Method of measurement

Serum levels of Bilirubin in blood tests

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After induction of anesthesia and intubation, they will receive 150 mg / kg n-acetylcysteine intravenously (Oxy-Nak, Elixir Pharmacy, Boroujerd, Iran).

Category

Prevention

2

Description

Control group: After induction of anesthesia and intubation, intravenous administration of 150 mg / kg normal saline will be given.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan Hospital

Full name of responsible person

Pegah Abbasi Hormozi

Street address

Golestan Hospital, Golestan Boulevard

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Phone

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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mohammad Badavi

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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

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Pegah Abbasi Hirmozi

Position

Associate Professor

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable