

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Evaluation of the effect of N-acetylcysteine (NAC) in cardio-pulmonary pump device in preventing kidney failure in coronary heart surgery

Protocol summary

Study aim

Evaluation of the effect of N-acetylcysteine (NAC) on preventing creatinine increase in open heart surgery

Design

Clinical trial with control and intervention group, with parallel, non-randomized, phase 3 groups per 100 patients

Settings and conduct

The present study is a non-randomized and non-blinding clinical trial that was performed in Chamran Hospital in 1398. The statistical population of patients are candidates for CABG surgery. The effect of N-acetylcysteine (NAC) on the prevention of renal failure in open heart surgery will be investigated. The study population is all patients who have referred to the cardiac operating room of Isfahan Chamran Hospital for CABG surgery

Participants/Inclusion and exclusion criteria

Entry requirements Age 40 to 65 years Kidney filtering speed (GFR) greater than 60 Creatinine less than 1.5 Having conscious satisfaction Patients who had no previous history of open heart surgery. Patients undergoing heart surgery (CABG). Patients who did not use extracellular membrane oxygenation (ECMO) and pump balloons before open heart surgery. No entry conditions Patients who are candidates for emergency CABG Patients who had valve surgery in addition to CABG surgery Patients undergoing CABG without a cardiopulmonary pump (CPB)

Intervention groups

The intervention group is given 1200 mg of NAC with Prime and the control group does not receive the drug

Main outcome variables

Kidney failure status

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200823048491N1**

Registration date: **2020-12-20, 1399/09/30**

Registration timing: **retrospective**

Last update: **2020-12-20, 1399/09/30**

Update count: **0**

Registration date

2020-12-20, 1399/09/30

Registrant information

Name

Leila Rostazadeh shekh yosefi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3532 0882

Email address

jebran.49@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-24, 1398/12/05

Expected recruitment end date

2020-12-19, 1399/09/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of N-acetylcysteine (NAC) in cardio-pulmonary pump device in preventing kidney failure in coronary heart surgery

Public title

The effect of N-acetylcysteine (NAC) on renal failure in Coronary surgery

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age 40 to 65 years GFR greater than 60 Creatinine less than 1.5 Having conscious satisfaction Patients with no previous history of open heart surgery Patients undergoing CABG coronary artery bypass graft surgery Patients who did not use ECMO and pump balloons before open heart surgery

Exclusion criteria:

Patients undergoing CABG without Cardiopulmonary pump (CPB) Patients who had valve surgery in addition to CABG surgery Patients who are candidates for emergency CABG

Age

From **40 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Isfahan University of Medical Sciences

Street address

Isfahan, Hezar Jerib St, Isfahan University of Medical Sciences

City

Esfahan

Province

Isfahan

Postal code

۷۳۴۶۱-۸۱۷۴۶

Approval date

2020-02-24, 1398/12/05

Ethics committee reference number

IR.MUI.MED.REC.1398.663

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

Patients undergoing open heart surgery

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Evaluation of BUN

Timepoint

One and two days after surgery

Method of measurement

Through blood tests and sheets available in the ICU

2**Description**

Creatinine

Timepoint

One and two days after surgery

Method of measurement

Through blood tests and sheets available in the ICU

3**Description**

Urinary output

Timepoint

One and two days after surgery

Method of measurement

Through blood tests and sheets available in the ICU

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group for patients taking 1200 mg of NAC once in prime during cardiopulmonary pumping 1200 mg of NAC

Category

Treatment - Drugs

2**Description**

Control group: For patients who are not taking NAC

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Chamran Hospital

Full name of responsible person

Leila Roustazadeh Sheikh Yousefi

Street address

Shahid Chamran Hospital ,Mushtaq 3rd Street Isfahan town

City

Esfahan

Province

Isfahan

Postal code

۷۳۴۶۱-۸۱۷۴۶

Phone

+98 31 3260 0961

Fax

+98 31 3260 0961

Email

dean@med.mui.ac.i

Web page address

<http://med.mui.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Vice Chancellor for Research and Technology

Street address

Isfahan Hezar Jerib St., Isfahan University of Medical Sciences and Health Services

City

Esfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 0048

Fax

+98 31 3668 8597

Email

dean@med.mui.ac.ir

Web page address

http://med.mui.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Leila Roustazadeh Sheikh Yousefi

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

Street address

Isfahan, third Mushtaq street, Zayandehrud town

City

Esfahan

Province

Isfahan

Postal code

8158345932

Phone

+98 31 3532 0882

Email

LEILAEOSTA3131@GMAIL.COM

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Leila Roustazadeh Sheikh Yousefi

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

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City

Esfahan

Province

Isfahan

Postal code

8158345932

Phone

+98 31 3532 0882

Email

leilaeosta3131@gmail.com

Person responsible for updating data**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

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Isfahan

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8158345932

Phone

+98 31 3532 0882

Email

leilarosta3131@gmail.com

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

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

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

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

Data Dictionary

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