

# 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**

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**Province**

Isfahan

**Postal code**

8158345932

**Phone**

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**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

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

Esfahan University of Medical Sciences

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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**

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