

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 2026

### Study of the changes in level of NGAL, biomarker of transplanted kidney function by application of N-acetyl cysteine in cadaveric renal transplant recipients

#### Protocol summary

##### Summary

This study is undertaken to evaluate the effect of acetylcysteine administration on delayed graft function and early outcomes of kidney transplantation in cadaveric renal transplant recipients. Seventy adult recipients of a deceased-donor kidney transplant will be randomized into two groups. The first group of patients will be treated with 600 mg acetylcysteine, one dose before transplantation and from the first day after transplantation, every 12 hours up to fifth day, in addition to standard treatment. The second group will receive placebo one dose before transplantation and then twice daily up to fifth day. For all patients entered the study, urinary and plasma neutrophil gelatinase-associated lipocalin (NGAL) concentrations as an early marker of delayed graft function, will be measured in designated times. Risk factors for delayed graft function will be compared in two groups and effectiveness of acetylcysteine in reducing delayed graft function will be determined.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014090214693N4**

Registration date: **2014-12-09, 1393/09/18**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2014-12-09, 1393/09/18

##### Registrant information

###### Name

Zahra Sahraei

##### Name of organization / entity

Faculty of pharmacy, Shahid beheshti university of medical sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8887 3704

##### Email address

z.sahraei@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Shahid Labbafinejad Medical Center and Urology and Nephrology Research Center, Shahid Beheshti Medical University, School of Pharmacy

##### Expected recruitment start date

2014-03-20, 1392/12/29

##### Expected recruitment end date

2015-09-21, 1394/06/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Study of the changes in level of NGAL, biomarker of transplanted kidney function by application of N-acetyl cysteine in cadaveric renal transplant recipients

##### Public title

Study of the effect of N-acetyl cysteine on biomarker of delayed graft function in cadaveric renal transplant recipients

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

inclusion criteria: kidney transplant recipients from deceased-donor; over 18 years of age exclusion criteria: Recent stroke; hyperoxaluria; Sensitivity to sulfonamides; PRA>30%; Second transplantation; Less than 2 cc urine volume before transplantation

#### Age

From **18 years** old to **75 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **70**

#### 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

Shahid Labbafinejad Medical Center and Urology and Nephrology Research Center

##### Street address

Pasdaran, Paidarfard avenue, Shahid Labbafinejad Medical Center and Urology and Nephrology Research Center

##### City

Tehran

##### Postal code

1666677951

#### Approval date

2014-03-13, 1392/12/22

#### Ethics committee reference number

20

## Health conditions studied

### 1

#### Description of health condition studied

Kidney transplant

#### ICD-10 code

Z94.0

#### ICD-10 code description

Kidney transplant status

## Primary outcomes

### 1

#### Description

urine and plasma NGAL

#### Timepoint

pre-transplantation, day 1 and 5 after transplantation

#### Method of measurement

ELISA kit

## Secondary outcomes

### 1

#### Description

need for dialysis in the first week post transplantation or creatinine reduction ratio less than 10% per day in 3 consecutive days after transplantation

#### Timepoint

daily

#### Method of measurement

laboratory reports for SrCr and clinical sign and symptoms for dialysis

## Intervention groups

### 1

#### Description

In control group placebo will administered one dose before transplantation and then twice per day from day one to five after transplantation

#### Category

Prevention

### 2

#### Description

In intervention group 600 mg acetylcysteine will administered one dose before transplantation and then twice per day from day one to five after transplantation

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahid Labbafinejad Hospital

##### Full name of responsible person

Dr Mohsen Nafar

##### Street address

##### City

Tehran

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Shahid Beheshti Medical University, School of Pharmacy and Shahid Labbafinejad Medical Center and Ur

**Full name of responsible person**

Dr Nafar

**Street address**

Pasdaran, Paidarfard avenue, Ninth boostan, Shahid Labbafinejad Hospital

**City**

Tehran

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Shahid Beheshti Medical University, School of Pharmacy and Shahid Labbafinejad Medical Center and Ur

**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**

School of pharmacy, Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Atieh Modarresi

**Position**

Resident of clinical pharmacy

**Other areas of specialty/work****Street address**

Niyayesh cross road, Valiasr st.

**City**

Tehran

**Postal code****Phone**

+98 21 8887 3704

**Fax****Email**

Atieh.modaresi@yahoo.com

**Web page address**

## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Labbafinejad Hospital and School of Pharmacy, Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Dr Mohsen Nafar, Dr Zahra Sahraei

**Position**

professor, assistant

**Other areas of specialty/work****Street address**

Pasdaran, Shahid Labbafinejad Hospital ,Niyayesh cross road, Valiasr st.

**City**

Tehran

**Postal code****Phone**

+98 21 8887 3704

**Fax****Email**

Nafar@sbmu.ac.irz.sahraei@sbmu.ac.ir

**Web page address**

## Person responsible for updating data

**Contact**

## 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*