

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### Study of the effect of N-acetyl cysteine on the renal graft function biomarkers (IL18, NGAL)

#### Protocol summary

##### Summary

This necessitates the studies and interventions to improve outcome of renal transplantation surgery. Delayed Graft Function (DGF) or delay in performance of transplanted kidney means absence of acceptable function in the renal activity in postgrafting phase. DGF is a consequence of ischemic and reperfusion injuries (IRI), and oxygen free radicals have a main role in pathophysiology of DGF. In meta-analysis studies, it has been demonstrated that DGF has a correlation with long and short time graft survival. Despite great advances in the transplantation procedure, dysfunction prevalence has not decreased. Major causes of this problem are the lack of appropriate markers for early diagnosis of DGF and on the other hand lack of appropriate and effective interventions to control DGF. Studies have shown that N-Acetyl Cysteine (NAC) can induce GSH synthesis, scavenger of free radicals, and infusion of NAC had similar effects as glutathione. This is a randomized clinical trial (RCT) on patients who have received kidney transplantation from living donors. Sixty transplanted patients will be randomized into 2 groups. The first group of patients will be treated with NAC 600mg 6 hr before transplantation and two doses of NAC 12 hours apart after transplantation in addition to standard treatment, and the second group will receive only standard antirejection treatment. For all patients entered the study, urinary concentrations of IL18 and NGAL will be measured in designated times. Risk factors of DGF will be compared in two groups and effectiveness of NAC in reducing DGF will be determined.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201109067490N1**

Registration date: **2011-10-11, 1390/07/19**

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

Last update:

Update count: **0**

##### Registration date

2011-10-11, 1390/07/19

##### Registrant information

###### Name

Zahra Sahraee

###### Name of organization / entity

School of pharmacy, Shahid Beheshti University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8887 3704

###### Email address

z.sahraee@sbmu.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Department of Nephrology, Shahid Labbafinejad Medical Center and Urology and Nephrology Research Center, Shahid Beheshti University of Medical Sciences; School of pharmacy, Shahid Beheshti University of Medical Sciences

##### Expected recruitment start date

2011-04-01, 1390/01/12

##### Expected recruitment end date

2012-11-01, 1391/08/11

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Study of the effect of N-acetyl cysteine on the renal graft function biomarkers (IL18, NGAL)

**Public title**

Study of the effect of N-acetyl cysteine on the renal graft function biomarkers (IL18, NGAL)

**Purpose**

Prevention

**Inclusion/Exclusion criteria**

Inclusion Criteria: patient receiving transplantation from living donors. Exclusion Criteria: having a neoplastic disease; brain tumor; having inflammatory diseases in their active phase (SLE); an acute infection, meningitis, sepsis; Sickle Cell Disease; Pregnancy; Cardio-renal syndrome; endogenous Cushing's syndrome; chronic use of cimetidine; a history of acute pancreatitis in recent months; Multiple Sclerosis; cardiac bypass in a recent month; cirrhosis due to Hepatitis C; having Alzheimer's disease; having a untreated major depressive illness or schizophrenia; Stroke in recent months; Hyperoxaluria sensitivity to sulfonamides.

**Age**

No age limit

**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)**

Single blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids****1****Registry name**

ClinicalTrial.gov

**Secondary trial Id**

NCT01403506

**Registration date**

2011-07-26, 1390/05/04

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

Shahid Labbafinejad Medical Center and Urology and Nephrology Research Center, Shahid Beheshti Unive

**Street address**

9 th Bostan, Pasdaran st.

**City**

Tehran

**Postal code****Approval date**

2011-01-03, 1389/10/13

**Ethics committee reference number**

13

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

Delayed graft function after kidney transplantation

**ICD-10 code**

N29.8\*

**ICD-10 code description**

Other disorders of kidney and ureter in other diseases classified elsewhere

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

IL 18, NGAL

**Timepoint**

4 and 24 hr after transplantation

**Method of measurement**

Elisa kit

**Secondary outcomes****1****Description**

dialysis requirement

**Timepoint**

60 days after transplantation

**Method of measurement**

observation

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

First group: 600 mg of N-acetyl Cysteine 6 hrs before renal transplantation, and 12 hrs and 18 hrs after renal transplantation

**Category**

Treatment - Drugs

**2****Description**

Second group: only standard antirejection treatment

**Category**

N/A

## 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**

Department of Nephrology, Shahid Labbafinejad  
Medical Center and Urology and Nephrology Research  
Cen

**Full name of responsible person**

Dr.Mohsen Nafar

**Street address**

9th Bostan, Pasdaran st.

**City**

Tehran

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Department of Nephrology, Shahid Labbafinejad Medical  
Center and Urology and Nephrology Research Cen

**Proportion provided by this source**

**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*

2

### Sponsor

**Name of organization / entity**

School of pharmacy, Shahid Beheshti University of  
Medical Sciences

**Full name of responsible person**

Dr. Jamshid Salamzadeh

**Street address**

Niyayesh cross road, Valiasr st.

**City**

Tehran

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor**

**organization/entity?**

Yes

**Title of funding source**

School of pharmacy, Shahid Beheshti University of  
Medical Sciences

**Proportion provided by this source**

**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**

Dr. Zahra Sahraee

**Position**

resident of clinical pharmacy

**Other areas of specialty/work**

**Street address**

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**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

School of Pharmacy, Shahid Beheshti University of  
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**Full name of responsible person**

Dr. Jamshid Salamzadeh

**Position**

associated professor

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**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*