

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

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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

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

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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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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