

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