Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)

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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 recepients from deceased-donor; over 18 years of age exclusion criteria: Recent stroke; hyperoxaluria; Sensitivity to sulfonamides; PRA>30%; Second transplantation; Less then 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, dar 1 and 5 after transplantation

Method of measurement
ELISA kit

Secondary outcomes

1

Description
need for dialysis in the firs 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
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Full name of responsible person
Dr Mohsen Nafar, Dr Zahra Sahraei
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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