Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jun 2026

Study of the effects of N-acetylcysteine on oxidative stress status of patients on maintenance-hemodialysis undergoing cadaveric kidney transplantation

Protocol summary

Summary

Objectives: The aim of the study is to assess the effect of N-acetylcysteine(NAC) on oxidative status of cadaveric kidney transplant recipients. Design: A prospective, randomized, placebo-controlled clinical trial is conducted on deceased donor kidney recipients in two specialized medical center in Tehran, Iran. Setting and conduct: Patients receive N-acetylcysteine or placebo in addition to immunosuppressant protocol including cyclosporine mycophenolate mofetil and corticosteroid. Major Inclusion and Exclusion criteria: Patients on maintenance hemodialysis who undergoing cadaveric renal transplantation. Intervention: Patients are randomly assigned to receive either NAC 600 mg or placebo one dose within 2 hours before transplantation followed by twice daily of the same dose up to the fifth day after transplantation. Main outcome measures (variables): Glutathione peroxidase (GPX) activity in erythrocytes and serum malondialdehyde (MDA) levels are measured at baseline (pre-transplant) and five days after transplantation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016081827346N4**
Registration date: **2016-09-18, 1395/06/28**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-09-18, 1395/06/28

Registrant information

Name

Shadi Ziaie

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 8887 3704

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2017-01-20, 1395/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study of the effects of N-acetylcysteine on oxidative stress status of patients on maintenance-hemodialysis undergoing cadaveric kidney transplantation

Public title

Study of N-acetylcysteine effects on oxidative stress markers and renal function in cadaveric kidney transplantation

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: "Patients on maintenance dialysis who

are undergoing cadaveric renal transplantation"
Exclusion criteria: "preemptive kidney transplantation (transplantation prior to initiation of dialysis), multi-organ transplants, second transplantation, history of using NAC within the month prior to operation, and history of sensitivity to sulfa drugs"

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: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
The randomization is performed using the RAND function in Microsoft Excel.

Secondary Ids

1

Registry name
-

Secondary trial Id
-

Registration date
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Shahid Beheshti University of Medical Science

Street address
Niayesh Highway, Valiasr Ave, Tehran

City
Tehran

Postal code
1985717443

Approval date
2014-06-15, 1393/03/25

Ethics committee reference number
153

Health conditions studied

1

Description of health condition studied
patients on maintenance-hemodialysis who are undergoing cadaveric kidney transplantation

ICD-10 code
Z94.0

ICD-10 code description
Kidney transplant status

Primary outcomes

1

Description
Glutathione peroxidase activity in erythrocytes and serum malondialdehyde levels

Timepoint
pre-transplantation and 5 days after transplantation

Method of measurement
Randox Laboratories commercial kits for Glutathione peroxidase and biochemical method for malondialdehyde

Secondary outcomes

1

Description
Serum creatinine

Timepoint
daily

Method of measurement
biochemical method

Intervention groups

1

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

Category
Prevention

2

Description
In control group placebo is 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
9th Boostan, Pasdaran St. Tehran
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dr Nima Naderi
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Niayesh Highway, Valiasr Ave, Tehran
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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
Vice chancellor for research, Shahid Beheshti University of Medical Sciences
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
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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