

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Aug 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)

Phone

+98 21 8887 3704

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shadiziaie@sbmu.ac.ir

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
Street address
Niayesh Highway, Valiasr Ave, Tehran
City
Tehran

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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Person responsible for updating data

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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