

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Effect of N-Acetyl cystein on residual renal function in chronic hemodialysis patients treated with low flux synthetic dialysis membrane

Protocol summary

Summary

1.Objectives:The main purpose of this study is to determine effect of N-Acetyl cystein on residual renal function in chronic hemodialysis patients treated with low flux synthetic dialysis membrane. 2. Design:This study is a randomized, triple-blind, placebo control uni-central study.The study includes 106 patients with ESRD and undergoing chronic hemodialysis. 3. Setting and conduct: patients were divided into two 53-member groups with meshing randomization method. NAC pill was fed to one group and placebo to another one. 4. Inclusion criteria: patients should be treated with hemodialysis for at least 1 year, having more than 100 ml urine in 24 hr, and should be under treated with hemodialysis 3-times a week. Exclusion criteria: patients who have been currently treated with diuretics or antioxidants such as NAC, vitamin C and vitamin E. 5.Intervention: In this study 53 patients received NAC and 53 ones received placebo. 6.Main outcome measurements: midweek interdialytic urine collection for the measurement of urine output, calculation of residual renal Kt/V and glomerular filtration rate(GFR) (before and after the intervention).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015122325675N1**

Registration date: **2016-01-30, 1394/11/10**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-01-30, 1394/11/10

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Ahvaz University of Medical Sciences

Expected recruitment start date

2016-01-21, 1394/11/01

Expected recruitment end date

2016-06-21, 1395/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of N-Acetyl cystein on residual renal function in chronic hemodialysis patients treated with low flux synthetic dialysis membrane

Public title

Effect of N_ acetyl cyctein on hemodialysis patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: patients were treated with hemodialysis for at least 1 year, having more than 100 ml urine in 24 hr, treated with hemodialysis 3-times a week. Exclusion criteria: patients were currently treated

with diuretics or antioxidants such as NAC, vitamin C and vitamin E.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **106**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Meshing randomization

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz University of Medical Sciences

Street address

Golestan Blv

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Ahvaz

Postal code

61357_15794

Approval date

2015-12-05, 1394/09/14

Ethics committee reference number

IR.AJUMS.REC.1394.471

Health conditions studied

1

Description of health condition studied

chronic hemodialysis patients

ICD-10 code

XIV

ICD-10 code description

N17_N19

Primary outcomes

1

Description

residual renal function

Timepoint

before intervention and one month after intervention

Method of measurement

midweek inter dialytic urine collection for measurement of urine output and calculation of residual renal kt/v and GFR

Secondary outcomes

empty

Intervention groups

1

Description

N_ acetyl cystein 600 mg ,from Osve company,oral twice daily for 4 weeks

Category

Treatment - Drugs

2

Description

Placebo compatible with available standard drug oral twice daily for 4 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Fahime Abaforush_ resident of internal medicine

Street address

Azadegan Blv

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Ahvaz University of Medical Sciences

Full name of responsible person

Dr Nader Saki

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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 of Ahvaz 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

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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