Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

comparison of the effectiveness of adding N-acetylcysteine to current standard treatment with standard treatment alone on improving residual renal function in chronic peritoneal and hemodialysis patients

Protocol summary

Summary

The aim of this study is to investigate the effect of N-acetyl cysteine on improvement of residual renal function in patients treated with hemodialysis and peritoneal dialysis. In a multicenter prospective trial, those patients with hemodialysis and peritoneal dialysis in Imam Khomeini, Amir alam, Sina hospitals also Urmia and Kerman medical centers who has been under dialysis for more than 3 months and residual urine output of at least 100 mL/24 hours are included in the study. Antioxidant consumption such as vitamins E and C cause exclusion of patients. The total number of 120 patients with above-mentioned features is included in the study. The patients are randomly assessed in 4 randomized blocks method in one of control or intervention groups. The study is designed as a single blind and the patients are incognizant of the intervention. About 60 patients in the control group receive standard treatment including antihypertensive, group B vitamins and statin or A.S.A if necessary. Moreover, about 60 patients in the intervention group as well as standard treatment receive effervescent tablets N-acetyl cysteine 1200 mg two times a day for 3 months. The amount of residual renal function before and after the medication is studied. In order to measure the amount of residual renal function, the amount of 24 hour urine and the mean of urea and creatinine clearance is calculated. Besides, the amount of KT/V is also calculated for each patient. The values will be compared before and after completion of intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014071418482N1**

Registration date: **2014-09-26, 1393/07/04**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-09-26, 1393/07/04

Registrant information

Name

Mahsa Abbaszadeh

Name of organization / entity

Tehran University of Medical Science

Country

Iran (Islamic Republic of)

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+98 21 8804 2456

Email address

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2014-08-17, 1393/05/26

Expected recruitment end date

2014-12-20, 1393/09/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison of the effectiveness of adding N-acetylcysteine to current standard treatment with standard treatment alone on improving residual renal

function in chronic peritoneal and hemodialysis patients

Public title
effect of N-acetylcysteine in the treatment of peritoneal dialysis and hemodialysis patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: treating with dialysis for more than 3 months ;having more than 100 mL urine in 24 hours. Exclusion Criteria: treating with dialysis for less than 3 months; having acute renal failure; being currently treated with antioxidants such as vitamins E, C.; being anuric (less than 100 mL urine in 24 hours).
Age
From **18 years** old to **80 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tehran University of Medical Science
Street address
Tehran University of Medical Science, Poursina street, Qods street, Keshavarz Blvd.
City
Tehran
Postal code
Approval date
2014-01-26, 1392/11/06
Ethics committee reference number
93-1-14-24508

Health conditions studied

1

Description of health condition studied
chronic kidney disease stage 5
ICD-10 code
N18.5
ICD-10 code description
Chronic kidney disease, stage 5

Primary outcomes

1

Description
24hr urine volume
Timepoint
days 0, 15, 30, 45, 60, 75, 90
Method of measurement
measuring 24hr urine volume with graded container

2

Description
Glomerular filtration rate (GFR)
Timepoint
before study (day 0)and at the end of study (day 90)
Method of measurement
24hr urine volume test and evaluating mean of urea and creatinin clearance according to formula in the questionaire

3

Description
KT/V
Timepoint
before study (day 0) and at the end of study (day 90)
Method of measurement
measuring urea before and after dialysis

Secondary outcomes

1

Description
fasting plasma glucose
Timepoint
before study and monthly till the end of the study
Method of measurement
laboratory

2

Description
gastrointestinal complication (nausea, vomiting, diarrhea)
Timepoint
patients visits
Method of measurement
asking from paitients

Intervention groups

1

Description
Control group received only standard treatment including antihypertensive drugs, vitamin B, statin, asprin for a period of three month.
Category
Treatment - Drugs

2

Description
Intervention group received eff tab NAC 1200 mg BD other than standard treatment (including antihypertensive drugs, vitamin B, statin, asprin) for three month.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini hospital, Dialysis ward
Full name of responsible person
Dr farrokhlagha ahmadi
Street address
Dialysis Ward, Imam Khomeini Hospital Complex - Keshavarz Blvd. - Tehran
City
Tehran

2

Recruitment center
Name of recruitment center
Amiralam hospital, Dialysis ward
Full name of responsible person
Dr Sima Maziyar
Street address
Hemodhalysis ward, Amir-Alam Hospital, Sadi Street, Ferdosi square.
City
Tehran

3

Recruitment center
Name of recruitment center
Sina hospital, Dialysis ward
Full name of responsible person
Dr effat Razeghi
Street address
Imam Khomeini Ave., Hasan Abad Sq., Sina Hospital. Tehran
City
Tehran

4

Recruitment center
Name of recruitment center
Urmia Imam Khomeini hospital, Dialysis ward
Full name of responsible person
Street address
MODARRES BOULEVARD, ERSHAD BOULEVARD, IMAM KHOMEINI HOSPITAL, URMIA, IRAN.
City
Urmia

5

Recruitment center
Name of recruitment center
Kerman hospital, Dialysis ward
Full name of responsible person
Street address
City
Kerman

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Science
Full name of responsible person
Doctor masoud Yonesian, Vice Chancellor for research
Street address
Tehran University of Medical Science, Poursina street, Qods street, Keshavarz Blvd., Tehran, Iran
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Science
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
Tehran University of Medical Science
Full name of responsible person
Dr mahsa abbaszadeh
Position

resident of internal medicine
Other areas of specialty/work
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Person responsible for scientific inquiries

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Name of organization / entity
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Person responsible for updating data

Contact
Name of organization / entity
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Dr mahsa abbaszadeh
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Other areas of specialty/work
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mahsa.abbaszadeh@yahoo.com
Web page address

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