

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 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)

Phone

+98 21 8804 2456

Email address

m-abbaszadeh@razi.tums.ac.ir

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 questionnaire

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 patients

Intervention groups

1

Description

Control group received only standard treatment including antihypertensive drugs, vitamin B, statin, aspirin 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, aspirin) 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

Hemodialysis 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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Other areas of specialty/work

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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