Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Effect of N-Acetylcystein on serum Malondialdehyde in comparison with placebo in chronic hemodialysis patients

Protocol summary

Summary

This study is a controlled, randomized, and double-blind clinical trial that was performed on 60 patients with renal failure aging over 16 and after three months of hemodialysis. All of the patients have been taken testimonial for both N-acetylcystein and placebo provided that, they do not know which group of study (experimental or control) they will be entered. Patients participating in this study, randomly select a numbered card in sealed envelopes in order to enter the control or the experimental group. Giving the medication and randomization process are done by someone who do not intervene in the experiment, accordingly, this study is double-blind. At the beginning of the study, total serum Malondialdehyde is measured as a basis and prior to the prescription of medication or placebo in both groups. Measurement of this marker is done through spectrophotometry method with malondialdehyde kit from merck company of Germany. Then the main group is given 600 mg of N-acetylcysteine twice daily (within 12 hours) for 6 weeks to be taken before meals. To Control the Correct use of medicines, pills and (placebos) are given to patients every week and at the weekend the empty blisters of pills are collected and counted. If a patient did not consume more than 20% of tablets, he would be excluded. The control group is given placebo tablets similar to N-acetylcysteine (2 times a day) within 12 hours in 6 weeks. Placebo was similar to that of N-acetylcysteine tablets in terms of shape, colour and flavour. Its components include: micro-crystalline, cellulose, lactose, corn starch, sorbitol and talc (2% of the total tablet weight). Upon completion of the study period (6 weeks), serum Malondialdehyde, in two groups are measured again using the above mentioned method. Finally, the collected data will be analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014031216969N1**
Registration date: **2014-07-31, 1393/05/09**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-07-31, 1393/05/09

Registrant information

Name
Ali Javaherforoushzadeh
Name of organization / entity
Ahvaz Jondishapour University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Ahvaz Jondishapour University Of Medical Science

Expected recruitment start date

2014-04-21, 1393/02/01

Expected recruitment end date

2014-06-05, 1393/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of N-Acetylcystein on serum Malondialdehyde in comparison with placebo in chronic hemodialysis

patients

Public title
Effect of N-Acetylcysteine in hemodialysis patients
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: 1) all of the chronic hemodialysis patients due to end stage renal disease more than 18 years old and at least three months has been past from starting of hemodialysis. Exclusion criteria: 1) Every acute disease leads to hospitalization from one month before trial. 2) Allergy to N-acetylcysteine. 3) Hepatic cirrhosis 4) Using Vitamin E or C or every known antioxidant from two weeks before intervention. 5) congestive heart failure or ejection fraction less than 35%. 6) Non using of N-acetylcysteine or placebo more than 20% of total drug.
Age
From **16 years** old to **100 years** old
Gender
Both

Phase
2
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

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Ahvaz Jondishapour University of Medical Sciences
Street address
Vice chancellery for Development, Research and Technology Ahvaz Jondishapour University of Medical Sciences, university city, Golestan St.
City
Ahvaz
Postal code
Approval date
2013-09-23, 1392/07/01
Ethics committee reference number
Ajums. Rec.1392.217

Health conditions studied

1

Description of health condition studied
Hemodialysis patients
ICD-10 code
N18
ICD-10 code description
Renal failure

2

Description of health condition studied
Hemodialysis patients
ICD-10 code
N19
ICD-10 code description
Renal failure

3

Description of health condition studied
Hemodialysis patients
ICD-10 code
N17
ICD-10 code description
Renal failure

Primary outcomes

1

Description
Serum Malondialdehyde
Timepoint
Before intervention and 6 weeks after intervention
Method of measurement
With malondialdehyde kit spectrophotometry method in mmol/lit

Secondary outcomes

1

Description
Itching
Timepoint
Before intervention and 6 weeks after intervention
Method of measurement
Visual

Intervention groups

1

Description
Intervention group: N-acetylcysteine with the trade name Fluimucil, as 600 milligram tablet, made by Swiss

Zambon Svizzerasa company, given twice daily (every 12 hours), per oral for 6 weeks.

Category

Treatment - Drugs

2

Description

Control group: Placebo as 600 milligram tablet, twice daily, every 12 hours, per oral for 6 weeks, made from micro-crystalline cellulose, lactose, corn starch, talk (2% of total tablet weight) which made in pharmacology school of Ahvaz Jondishapour University of Medical Sciences.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Hemodialysis ward of Imam khomeyni Hospital

Full name of responsible person

Shokouh Shayanpour

Street address

Azadegan St. Imam khomeyni Hospital, hemodialysis ward

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Development, Research and Technology of Ahvaz Jondishapour University of Medical

Full name of responsible person

Dr.saki nader

Street address

Golestan St. Vice Chancellor for Development, Research and Technology of Ahvaz Jondishapour University of Medical Sciences, University city

City

Ahvaz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for Development, Research and Technology of Ahvaz Jondishapour University of Medical

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

Ahvaz Jondishapour University of Medical Sciences

Full name of responsible person

Ali Javaherforoushzadeh

Position

Resident of Internal Medicine

Other areas of specialty/work

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Associated Professor

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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