

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation the effect of oral N-acetylcysteine on quantitative serum high sensitivity CRP and hemoglobin in end stage renal disease patients under hemodialysis

Protocol summary

Summary

The aim of this study is to evaluate the effect of N-acetylcysteine on quantitative serum high sensitivity CRP and hemoglobin in end stage renal disease patients under emodialysis who referred to Imam Khomeini hospital and Boo-Ali hospital, Ardabil, Iran. Total of 40 patients with positive CRP who were dialyzed at least three times per week for three months were selected and divided in two intervention and control groups randomly. Patients with chronic inflammatory diseases such as rheumatoid arthritis and lupus, patients who take HRT drugs during menopause, patients with malignant blood diseases such as myelodysplastic syndrome, lymphoma, leukemia, bone marrow aplasia and patients with HIV were excluded from the study. Ferritin, Albumin, Hct, Hgb and Hs CRP were checked before and after intervention for all patients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016111030821N1**

Registration date: **2017-03-16, 1395/12/26**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-03-16, 1395/12/26

Registrant information

Name

Roya Alaei

Name of organization / entity

Ardabil University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 45 1552 3386

Email address

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Ardabil University of Medical Sciences

Expected recruitment start date

2016-10-20, 1395/07/29

Expected recruitment end date

2017-06-20, 1396/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of oral N-acetylcysteine on quantitative serum high sensitivity CRP and hemoglobin in end stage renal disease patients under hemodialysis

Public title

The effect of oral N-acetylcysteine on quantitative serum high sensitivity CRP and hemoglobin in hemodialysis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with positive CRP who were dialyzed at least three times per week for three months

Exclusion criteria: Patients with chronic inflammatory diseases such as rheumatoid arthritis and lupus, patients who take HRT drugs during menopause ,patients with

malignant blood diseases such as myelodysplastic syndrome, lymphoma, leukemia, bone marrow aplasia and patients with HIV

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **40**

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 Ardabil University of Medical Sciences

Street address

Daneshgah st. Ardabil University of Medical Sciences

City

Ardabil

Postal code

56189-85991

Approval date

2016-08-19, 1395/05/29

Ethics committee reference number

IR.ARUMS.REC1395-53

Health conditions studied

1

Description of health condition studied

End stage renal disease

ICD-10 code

N 18.5

ICD-10 code description

End stage kidney disease

Primary outcomes

1

Description

CRP

Timepoint

Before the intervention and one month after intervention

Method of measurement

ELIZA

Secondary outcomes

1

Description

Hemoglobin

Timepoint

Before the intervention and one month after intervention

Method of measurement

CBC

Intervention groups

1

Description

Intervention group: N-acetylcysteine tab, 600 mg bid for 1 month period

Category

Treatment - Drugs

2

Description

Control group: placebo tab bid, for 1 month period

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Roya Alaei

Street address

Daneshgah St. Ardabil University of Medical Sciences

City

Ardabil

2

Recruitment center

Name of recruitment center

Boo-Ali Hospital

Full name of responsible person

Roya Alaei

Street address

Daneshgah St. Ardabil University of Medical Sciences

City
Ardabil

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for research of Ardabil University of Medical Sciences
Full name of responsible person
Afshan Sharghi
Street address
Daneshgah St. Ardabil University of Medical Sciences
City
Ardabil

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 Ardabil 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

Name of organization / entity
Ardabil University of Medical Sciences
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Person responsible for updating data

Contact

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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