

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Jun 2026

### The effect of oral N-acetyl cystein on inflammatory markers in hemodialysis patients

#### Protocol summary

##### Summary

This study is a randomized clinical trial that designed to assess effect of oral N-acetyl cystein in 32 hemodialysis patients referred to Sadoughi and Rahneem hospital in yazd. Inclusion criteria include: patients undergone hemodialysis that received hemodialysis for more than 3 month with 3 sessions per week. Exclusion criteria include: Patients undergone hemodialysis with venous catheter; symptoms of active infection in one month before starting the study and during the study; rising liver enzymes(ALT and AST); blood transfusion during the study; collagen vascular diseases were the etiology of end stage renal disease; age lesser than 18 -year- old, use of corticosteroid and immunosuppressive drugs; history of myocardial infarction or stroke in 3 month before starting the study; history of intolerance or allergy to NAC. Patients will be given NAC, effervescent tablet 600 miligram twice daily for 2 months. Blood samples will collect at the beginning and end of the study before initiation of dialysis for testing HbA1C, total cholesterol, triglyceride, albumine, calcium, phosphor, Malondialdehyde (MDA) and highly sensitive CRP (hs CRP).

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016111529812N2**

Registration date: **2016-12-14, 1395/09/24**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-12-14, 1395/09/24

##### Registrant information

##### Name

Roya Hemayati

##### Name of organization / entity

Shahid Sadoughi University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 35 3724 0171

##### Email address

drhemayati@ssu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor for Research and Technology Yazd  
University of Medical Sciences

##### Expected recruitment start date

2014-03-16, 1392/12/25

##### Expected recruitment end date

2014-12-22, 1393/10/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of oral N-acetyl cystein on inflammatory markers in hemodialysis patients

##### Public title

effect of oral NAC in hemodialysis patients

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

Inclusion criteria: patients undergone hemodialysis that received hemodialysis for more than 3 month with 3 sessions per week. Exclusion criteria: Patients undergone hemodialysis with venous catheter; symptoms of active infection in one month before starting the study and

during the study; rising liver enzymes(ALT and AST); blood transfusion during the study; collagen vascular diseases were the etiology of end stage renal disease; age lesser than 18 -year- old, use of corticosteroid and immunosuppressive drugs; history of myocardial infarction or stroke in 3 month before starting the study; history of intolerance or allergy to NAC.

#### **Age**

From **18 years** old

#### **Gender**

Both

#### **Phase**

N/A

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **26**

#### **Randomization (investigator's opinion)**

N/A

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Not blinded

#### **Blinding description**

#### **Placebo**

Not used

#### **Assignment**

Single

#### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### **1**

#### **Ethics committee**

##### **Name of ethics committee**

Ethics committee of ShahidSadoughi University of Medical Sciences, Yazd

##### **Street address**

Bahonar Square, Yazd, Central Organization of Shahid Sadoughi University of Yazd Medical Sciences and Health Services

##### **City**

Yazd

##### **Postal code**

8916978477

#### **Approval date**

2014-03-11, 1392/12/20

#### **Ethics committee reference number**

17/1/257428

## **Health conditions studied**

### **1**

#### **Description of health condition studied**

Nephropathy

#### **ICD-10 code**

Z49.1

#### **ICD-10 code description**

Extracorporeal dialysis

## **Primary outcomes**

### **1**

#### **Description**

Hs-CRP

#### **Timepoint**

At baseline and Two months after the initiation of trial

#### **Method of measurement**

Mg/dl

### **2**

#### **Description**

MDA

#### **Timepoint**

At baseline and Two months after the initiation of trial

#### **Method of measurement**

μmol/dl

### **3**

#### **Description**

Albumin

#### **Timepoint**

At baseline and Two months after the initiation of trial

#### **Method of measurement**

g/dl

### **4**

#### **Description**

Cholesterol

#### **Timepoint**

At baseline and Two months after the initiation of trial

#### **Method of measurement**

Mg/dl

### **5**

#### **Description**

Triglycerides

#### **Timepoint**

At baseline and Two months after the initiation of trial

#### **Method of measurement**

Mg/dl

### **6**

#### **Description**

Hb-A1C

#### **Timepoint**

At baseline and Two months after the initiation of trial

#### **Method of measurement**

g/dl

### **7**

#### **Description**

Calcium  
**Timepoint**  
At baseline and Two months after the initiation of trial  
**Method of measurement**  
Mg/dl

**8**

**Description**  
Phosphorus  
**Timepoint**  
At baseline and Two months after the initiation of trial  
**Method of measurement**  
Mg/dl

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**  
intervention(NAC, 600 mg, twice daily, for two months)  
**Category**  
Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**  
**Name of recruitment center**  
Shahid Rahnemoun Hospital-Yazd  
**Full name of responsible person**  
Roya Hemayati  
**Street address**  
Farokhi Street, Shahid Rahnemoun Hospital  
**City**  
Yazd

## Sponsors / Funding sources

**1**

**Sponsor**  
**Name of organization / entity**  
Vice Chancellor for research of University of Medical Sciences and Health Services, Yazd  
**Full name of responsible person**  
Mehrpavar Hoshang  
**Street address**  
Bahonar Sq, Yazd  
**City**  
Yazd  
**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 University of Medical Sciences and Health Services, Yazd  
**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**  
Nephrology Department, Shahid Sadoughi University of Medical Sciences, Yazd, Iran  
**Full name of responsible person**  
Farzaneh Najafee  
**Position**  
Nephrologist, Assistant Professor  
**Other areas of specialty/work**  
**Street address**  
Shahid Sadoughi hospital, Shahid Ghandi bulvar, Yazd, Iran  
**City**  
Yazd  
**Postal code**  
**Phone**  
+98 35 3822 4001  
**Fax**  
**Email**  
farzaneh najafee@yahoo.com  
**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Shahid Sadoughi hospital  
**Full name of responsible person**  
Roya Hemayati  
**Position**  
Nephrologist, Assistant Professor  
**Other areas of specialty/work**  
**Street address**  
Shahid Sadoughi hospital, Shahid Ghandi bulvar, Yazd, Iran  
**City**  
Yazd  
**Postal code**  
**Phone**  
+98 35 3822 4001  
**Fax**  
**Email**  
hemayatiroya@gmail.com  
**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Diabetes Research Center

**Full name of responsible person**

Saeedeh Jam-Ashkezari

**Position**

MA.Mycology

**Other areas of specialty/work****Street address**

Tallar Honar Alley, Bahonar Square, Yazd

**City**

Yazd

**Postal code**

8917945556

**Phone**

+98 35 3728 0217

**Fax**

+98 35 3728 0216

**Email**

saeedehjam@ut.ac.ir

**Web page address**

<http://ijdo@ssu.ac.ir>

## 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*