# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

29 Jul 2026

## evaluation of the effect of oral N-acetylcysteine on nitrosative stress factors in patients with rheumatoid arthritis

## Protocol summary

**Summary**

The purpose of this study is evaluation of the effect oral N-acetylcysteine (NAC) on nitrosative stress factors in patients with rheumatoid arthritis. This study is a randomized double blind clinical trial on 52 patients with active rheumatoid arthritis. Patients with active rheumatoid arthritis with Normal renal function(serum creatinine lower than 2) and Normal liver function with Ability of taking oral NAC are included in this study. Patients are divided into intervention group and placebo group. Intervention group will receive 600 mg NAC twice daily for 12 weeks and placebo group will receive placebo for the same duration as an adjuvant beside the standard treatment. NAC is an antioxidant agent. It reduces nitrosative and oxidative stress. At baseline and at the end of the study patients blood samples will be examined to evaluate the nitrosative stress factors.

## General information

**Acronym**

-

**IRCT registration information**

IRCT registration number: **IRCT2017073022965N12**
Registration date: **2017-08-12, 1396/05/21**
Registration timing: **prospective**

Last update:
Update count: **0**

**Registration date**

2017-08-12, 1396/05/21

**Registrant information**

**Name**

Maryam Mehrpooya

**Name of organization / entity**

School of Pharmacy,Hamadan University of Medical Sciences

**Country**

Iran (Islamic Republic of)

**Phone**

+98 81 3821 8684

**Email address**

m.mehrpoya@umsha.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

Vice chancellor of research, Hamedan University of Medical Sciences

**Expected recruitment start date**

2017-08-21, 1396/05/30

**Expected recruitment end date**

2018-08-20, 1397/05/29

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

evaluation of the effect of oral N-acetylcysteine on nitrosative stress factors in patients with rheumatoid arthritis

**Public title**

evaluation of N-acetylcysteine on nitrosative stress in Rheumatoid arthritis patients

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

inclusion criteria: Patients with active rheumatoid arthritis; Normal renal function(serum creatinine lower than 2); Ability of taking oral n-acetylcysteine; Normal liver function exclusion criteria: Renal dysfunction; Liver dysfunction; Active infection; Mental or cognitive problem; Disability of taking oral drug; Taking antioxidant agents or anti-inflammatory drugs in

previous month; Patients with other inflammatory diseases; Patients whom experience adverse drug reactions; Pregnant or lactating patients

**Age**
From **18 years** old to **65 years** old

**Gender**
Both

**Phase**
3

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **52**

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

**Randomization description**

**Blinding (investigator's opinion)**
Double blinded

**Blinding description**

**Placebo**
Used

**Assignment**
Parallel

**Other design features**
Patients are assigned into intervention or placebo groups by block randomization method.

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Ethics Committee of the Hamedan University of Medical Sciences

**Street address**
Hamedan University of Medical Sciences, In front of Luna park, Pazhouhesh Cross , Hamadan

**City**
Hamedan

**Postal code**

**Approval date**
2017-07-08, 1396/04/17

**Ethics committee reference number**
IR.UMSHA.REC.1396.308

## Health conditions studied

### 1

**Description of health condition studied**
Rheumatoid arthritis

**ICD-10 code**
M06.9

**ICD-10 code description**
Rheumatoid arthritis, unspecified

## Primary outcomes

### 1

**Description**
nitric oxide

**Timepoint**
at baseline, at the end of study

**Method of measurement**
serum level

### 2

**Description**
Lipid peroxidation

**Timepoint**
at baseline, at the end of study

**Method of measurement**
serum level

### 3

**Description**
Thiol groups

**Timepoint**
at baseline, at the end of study

**Method of measurement**
serum level

### 4

**Description**
Total antioxidant capacity

**Timepoint**
at baseline, at the end of study

**Method of measurement**
serum level

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
intervention group: N-acetylcysteine 600 mg twice daily for 12 weeks

**Category**
Treatment - Drugs

### 2

**Description**
control group: Placebo twice daily for 12 weeks

**Category**
Placebo

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Besat Hospital
**Full name of responsible person**
Ahmad Tahammoli Roudsari
**Street address**
Besat hospital, Shahid Motahari Avenue, Hamedan
**City**
Hamedan

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Vice Chancellor for research of Hamadan University of Medical Sciences
**Full name of responsible person**
Alireza Ahmadi
**Street address**
Hamedan University of Medical Sciences, In front of Luna park, Pazhouhesh Cross , Hamadan
**City**
Hamedan
**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 Hamadan 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**
Hamedan University of Medical Sciences
**Full name of responsible person**
Maryam Mehrpooya
**Position**
Assistant Professor/ PhD of clinical pharmacy
**Other areas of specialty/work**
**Street address**
Hamedan University of Medical Sciences, In front of Luna park, Pazhouhesh Cross , Hamadan
**City**
Hamedan
**Postal code**
**Phone**
+98 81 3838 1594
**Fax**
**Email**
m.mehrpoya2003@yahoo.com
**Web page address**

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Hamedan University of Medical Sciences
**Full name of responsible person**
Maryam Mehrpooya
**Position**
Assistant Professor/ PhD of clinical pharmacy
**Other areas of specialty/work**
**Street address**
Hamedan University of Medical Sciences, In front of Luna park, Pazhouhesh Cross , Hamadan
**City**
Hamedan
**Postal code**
**Phone**
+98 81 3838 1594
**Fax**
**Email**
m.mehrpoya2003@yahoo.com
**Web page address**

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Hamedan University of Medical Sciences
**Full name of responsible person**
Fateme Yasrebifar
**Position**
student
**Other areas of specialty/work**
**Street address**
Hamedan University of Medical Sciences, In front of Luna park, Pazhouhesh Cross , Hamadan
**City**
Hamedan
**Postal code**
**Phone**
+98 21 4473 6694
**Fax**
**Email**
fateme.yasrebifar@gmail.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*