Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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