

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Evaluating the effects of oral N-acetyl cysteine as a Adjuvant therapy on controlling clinical symptoms and serum level of inflammatory biomarkers including IL6,TNF- α , CRP and ESR in rheumatoid arthritis Patients

Protocol summary

Summary

This study is a randomized, placebo-controlled, double-blind trial in 70 patients with arthritis rheumatoid that referred to Besat hospital of hamedan. Inclusion criteria: Patients with diagnosis of active arthritis rheumatoid; Patients more than 18 years and less than 65 years; Patients with moderate to severe active disease
Exclusion criteria: Patients with active infection; Patients with mild active disease. Patients will be randomly allocated into two groups (intervention and placebo) according to Random number tables. In intervention group, patients in addition to standard regimen for RA will receive NAC 600 mg twice a day for 12 weeks and placebo group will receive standard regimen with placebo. Disease Activity Score, version 28 is based on VAS, ESR and number of involved joints and IL-6,TNF- α are evaluated before treatment and after 12 weeks after treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015071722965N2**
Registration date: **2015-11-06, 1394/08/15**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-11-06, 1394/08/15

Registrant information

Name

Maryam Mehrpooya

Name of organization / entity

School of Pharmacy, Hamadan University of Medical

Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Hamadan University of medical Sciences

Expected recruitment start date

2015-01-09, 1393/10/19

Expected recruitment end date

2016-06-08, 1395/03/19

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the effects of oral N-acetyl cysteine as a Adjuvant therapy on controlling clinical symptoms and serum level of inflammatory biomarkers including IL6,TNF- α , CRP and ESR in rheumatoid arthritis Patients

Public title

Effect of N-acetyl cysteine on controlling clinical symptoms and inflammatory biomarkers in rheumatoid arthritis Patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Patients with diagnosis of arthritis rheumatoid; Patients more than 18 years and less than 65

years; Patients with moderate to severe active disease
Exclusion criteria: Patients with active infection; Patients with mild active disease

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **70**

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 Hamadan University of Medical Sciences

Street address

Hamadan University of Medical Sciences, Ayatollah kashani,

City

Hamadan

Postal code

Approval date

2015-11-20, 1394/08/29

Ethics committee reference number

IR.UMSHA.REC.1394.266

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

IL-6,TNF-alfa

Timepoint

Baseline, after 12 months

Method of measurement

serum level

Secondary outcomes

1

Description

Assesment of clinical symptoms

Timepoint

Baseline, after 12 months

Method of measurement

Disease Activity Score, version 28 questionnaire

Intervention groups

1

Description

Intervention group: Standard regimen plus NAC 600 mg twice daily for 12 months

Category

Prevention

2

Description

Control group: Standard regimen without NAC

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital

Full name of responsible person

Street address

Besat hospital,Shahid Motahari Avenue, Hamedan

City

Hamedan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Hamadan University of Medical Sciences

Full name of responsible person

Alireza Ahmadi
Street address
 Hamadan University of Medical Sciences
City
 Hamadan
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, 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

Person responsible for scientific inquiries

Contact

Name of organization / entity
 School of Pharmacy, Hamadan University of Medical Sciences
Full name of responsible person

Maryam Mehrpooya
Position
 Assistant Professor
Other areas of specialty/work
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Web page address

Person responsible for updating data

Contact

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