Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Jul 2026

Evaluating the effects of oral N-acetyl cysteine as a Adjuvant therapy on controling clinical symtoms and serum level of inflammatory biomarkers including IL6,TNF-α, CRP and ESR in rhumatoid 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-alfa 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

+98 81 3821 8684

Email address

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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 controling clinical symtoms and serum level of inflammatory biomarkers including IL6,TNF-α, CRP and ESR in rhumatoid arthritis Patients

Public title

Effect of N-acetyl cysteine on controling clinical symtoms and inflammatory biomarkers in rhumatoid arthritis Patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Patients with diagnosis of arthritis rhumatoid; 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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Hamedan University of Medical Sciences,Shahid Fahmide Avenue , Hamedan

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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