

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Evaluation the Effect of N-acetylcysteine on Inflammatory Biomarkers and Disease Activity Score (DAS28-ESR) of Rheumatoid Arthritis

Protocol summary

Study aim

Determination the effects of n-acetylcysteine on inflammatory biomarkers and disease activity score (DAS28-ESR) of Rheumatoid Arthritis

Design

A randomized double blind clinical trial with a control, parallel groups will be performed on 76 patients with rheumatoid arthritis in the 3rd phase of the trial within 10 months.

Settings and conduct

Patients with rheumatoid arthritis referred to the outpatient rheumatology clinic of Loghman Hakim Educational Hospital who are eligible to enter the study are randomly divided into DMARDs+placebo or DMARDs+oral n- acetylcysteine. Patients will be followed up at the four-week intervals and will receive free visits and drug in the clinic of rheumatology. In addition, patient, researcher, clinical caregiver and analyst are blind.

Participants/Inclusion and exclusion criteria

Rheumatoid arthritis patients with a DAS28-ESR ≥ 2.6 , no history of consuming antioxidant supplements within last 2 months, no recent infectious disease and patients under treatment with DMARDs

Intervention groups

Patients with inclusion criteria are randomly assigned to either DMARDs+placebo twice daily or DMARDs+oral N-acetylcysteine 600 milligrams twice daily.

Main outcome variables

IL-1, IL-17, DAS28-ESR patient global assessment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190626044030N1**

Registration date: **2019-12-25, 1398/10/04**

Registration timing: **registered_while_recruiting**

Last update: **2019-12-25, 1398/10/04**

Update count: **0**

Registration date

2019-12-25, 1398/10/04

Registrant information

Name

Faezeh Jamali

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-23, 1398/05/01

Expected recruitment end date

2020-05-21, 1399/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the Effect of N-acetylcysteine on Inflammatory Biomarkers and Disease Activity Score (DAS28-ESR) of Rheumatoid Arthritis

Public title

N-acetylcysteine in Rheumatoid Arthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Rheumatoid arthritis patients with a DAS28-ESR score ≥ 2.6 No history of consuming antioxidant supplements within last 2 months No change of the type and dose of patient's drugs in the last 1 month No recent infectious disease Patients that are under treatment with DMARDs	Tehran Province Tehran Postal code 1467664961
Exclusion criteria: Biologic agents therapy in the last 6 months Patients with concurrent autoimmune, rheumatoid disease and gout Using other complementary and alternative medicine Pregnancy and lactation Any addiction to psychotropic agents and opioids Uncontrolled hypertension Active gastrointestinal ulcer History of severe skin allergy Consuming nitroglycerin	Approval date 2019-06-12, 1398/03/22 Ethics committee reference number IR.SBMU.PHARMACY.REC.1398.078
Age From 18 years old Gender Both Phase 3 Groups that have been masked	Health conditions studied <u>1</u> Description of health condition studied Rheumatoid arthritis ICD-10 code ICD-10 code description
• Participant • Care provider • Investigator • Outcome assessor • Data analyser	Primary outcomes <u>1</u> Description IL-1, IL-17, DAS28-ESR, patient global assessment Timepoint Base, the end of the fourth week, the end of the eighth week Method of measurement Serum level, clinical signs, DAS28-ESR questionnaire
Sample size Target sample size: 76 Randomization (investigator's opinion) Randomized Randomization description We use simple individual random method in this study. Blinding (investigator's opinion) Double blinded Blinding description In our study, participants, researchist (clinical pharmacist) and physician are blind. Placebo Used Assignment Parallel Other design features	Secondary outcomes <u>1</u> Description ESR, Number of tender joints, number of swollen joints, reduced or increased need for oral or injectable corticosteroids Timepoint Baseline, at the end of the fourth week, at the end of the eighth week Method of measurement Serum level, clinical examination
Secondary Ids empty	Intervention groups
Ethics committees <u>1</u> Ethics committee Name of ethics committee Iran National committee for Ethics in Biomedical Research Street address Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafshan & South Falamak, Qods Town City	<u>1</u> Description Intervention group: The routine DMARDs in addition to 600 milligrams of effervescent of n-acetylcysteine(osve pharmaceutical company), twice daily for two months. Before intervention, at the end of first month and second month of consumption, we will take blood sample for the measurement of serum level of IL-1, 17 and ESR. Physical examination for calculate DAS-28 ESR will be done, too. Category Treatment - Drugs

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Description

Control group: The routine DMARDs in addition to effervescent of placebo (of pharmaceutical company) ,twice daily for two months. Before intervention, at the end of first month and second month of consumption, we will take blood sample for the measurement of serum level of IL-1, 17 and ESR. Physical examination for calculate DAS-28 ESR will be done, too.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Outpatient Rheumatology Clinic Loghman Hakim Educational Hospital

Full name of responsible person

Faezeh Jamali

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Jamshid Salamzadeh

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available