Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
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Iran (Islamic Republic of)
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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

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

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

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 Ids

empty

Ethics committees

1

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 Zarafashan & South Falamak, Qods Town

City

Tehran

Province

Tehran

Postal code

1467664961

Approval date

2019-06-12, 1398/03/22

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1398.078

Health conditions studied

1

Description of health condition studied

Rheumatoid arthritis

ICD-10 code

ICD-10 code description

Primary outcomes

1

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

Secondary outcomes

1

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

Intervention groups

1

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

2

Description
Control group: The routine DMARDs in addition to effervescent of placebo(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
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Outpatient Rheumatology Clinic Loghman Hakim Educational Hospital

Full name of responsible person
Faezeh Jamali

Street address
Logman Hakim hospital, Makhsous Ave., Lashgar Intersection

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loghman.hospital@sbmu.ac.ir

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http://lhmc.sbmu.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Afshin Zarghi

Street address
Arabi Ave, Daneshjoo Blvd, Velenjak

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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
Medical Pharmacy

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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