

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jun 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  $\geq 2.6$ , 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)

###### Phone

+98 21 8820 0118

###### Email address

f.jamali@sbmu.ac.ir

##### 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  $\geq 2.6$  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

##### City

Tehran

##### Province

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##### Postal code

1333631151

##### Phone

+98 21 5541 9423

##### Email

loghman.hospital@sbmu.ac.ir

##### Web page address

<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

##### City

Tehran

##### Province

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##### Postal code

1985717443

##### Phone

+98 21 2243 9770

##### Email

Intl\_office@sbmu.ac.ir

##### Web page address

<https://www.sbmu.ac.ir/>

#### 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

##### Street address

Faculty of Pharmacy, Niayesh Intersection ,Valieasr Ave.

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1991953381

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j.salamzadeh@yahoo.com

## Person responsible for scientific inquiries

#### Contact

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##### Latest degree

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## Person responsible for updating data

### Contact

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Shahid Beheshti University of Medical Sciences  
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Faezeh Jamali  
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Resident  
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f.jamali@sbm.ac.ir

## 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