

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Study effect of N-acetylcysteine on clinical status and paraclinical outcomes in patients with rheumatoid arthritis

Protocol summary

Study aim

Investigation of the effect of N-acetylcysteine on clinical and paraclinical findings in patients with rheumatoid arthritis

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 74 patients.

Settings and conduct

This double-blind clinical trial study will be performed on 74 patients with rheumatoid arthritis. First, patients with rheumatoid arthritis referred to the rheumatology clinic of Shahid Beheshti Hospital in Kashan will be identified based on diagnostic criteria and will be randomly assigned to receive N-acetylcysteine or placebo for 12 weeks. Anthropometric indices at the beginning and 12 weeks after the intervention will be compared.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patient with rheumatoid arthritis who aged 20 to 70 Years old Exclusion criteria: Unwillingness to cooperate, hypo or hyperthyroidism use of any supplements (vitamins, minerals and etc) within 3 months prior to enrollment in the study, incidence of intolerable complications and current smokers

Intervention groups

In this study, N-acetylcysteine tablets will be given to the intervention group and placebos that are similar in shape, color and other characteristics to N-acetylcysteine will be given to the control group.

Main outcome variables

Disease activity (DAS28-ESR) hs-CRP ESR

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20101014004934N2**

Registration date: **2020-11-25, 1399/09/05**

Registration timing: **prospective**

Last update: **2020-11-25, 1399/09/05**

Update count: **0**

Registration date

2020-11-25, 1399/09/05

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

5550030-0361

Email address

kamalesalatmanesh@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-30, 1399/09/10

Expected recruitment end date

2021-01-19, 1399/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study effect of N-acetylcysteine on clinical status and paraclinical outcomes in patients with rheumatoid arthritis

Public title

Investigation of the effect of N-acetylcysteine in rheumatoid arthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patient with rheumatoid arthritis 20 to 70 Years old

Exclusion criteria:

Unwillingness to cooperate Hypo or hyperthyroidism Use of any supplements (vitamins, minerals and etc) within 3 months prior to enrollment in the study Incidence of intolerable complications Current smokers

Age

From **20 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **74**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly assigned to a treatment group or placebo based on randomly generated numbers (1 to 74) from the website at (<https://stattrek.com/statistics/random-number-generator.aspx>). Also, to achieve two equal groups in terms of number of participants, the block randomization method with a ratio of 1 to 1 will be used. Drugs and placebos will be packaged in the same packages by a third party who has no role in the study and only a special code will be written on them. The patients and the investigators will be unaware of the type of intervention and after the end of the study, the codes will be decoded.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants, investigators, and outcome assessors will be unaware of the type of intervention until the end of the study. This will be done by encrypting the drug and placebo packages by a third party who has no role in the study, and the codes will be decrypted at the end of the study.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kashan University of Medical Sciences

Street address

Kashan University of Medical Sciences, Pezeshk Boulevard, Ghotbe Ravandi Boulevard, Kashan, Iran

City

Kashan

Province

Isfahan

Postal code

87159/81151

Approval date

2020-07-13, 1399/04/23

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1399.050

Health conditions studied

1

Description of health condition studied

Rheumatoid arthritis

ICD-10 code

M05

ICD-10 code description

Rheumatoid arthritis with rheumatoid factor

Primary outcomes

1

Description

Disease activity

Timepoint

At the beginning of the study (before the intervention) and 12 weeks after the intervention

Method of measurement

DAS28-ESR (using a questionnaire for VAS and a checklist to note physical examination results)

2

Description

hs-CRP

Timepoint

At the beginning of the study (before the intervention) and 12 weeks after the intervention

Method of measurement

Elisa kit

3

Description

ESR

Timepoint

At the beginning of the study (before the intervention) and 12 weeks after the intervention

Method of measurement

mm/h

Secondary outcomes

1

Description

Malondialdehyde

Timepoint

At the beginning of the study (before the intervention) and 12 weeks after the intervention

Method of measurement

Spectrophotometry

2

Description

Glutathione

Timepoint

At the beginning of the study (before the intervention) and 12 weeks after the intervention

Method of measurement

Spectrophotometry

3

Description

Total antioxidant capacity

Timepoint

At the beginning of the study (before the intervention) and 12 weeks after the intervention

Method of measurement

Spectrophotometry

4

Description

Morning stiffness duration

Timepoint

At the beginning of the study (before the intervention) and 12 weeks after the intervention

Method of measurement

Minutes

Intervention groups

1

Description

Intervention group: one tablet (600 mg) of N-acetylcysteine (Osvah, Iran) daily

Category

Treatment - Drugs

2

Description

Control group: Patients receiving one placebo tablet daily (Barij Essence, Iran)

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Alireza Jamali

Street address

Shahid Beheshti Hospital, Qotb-e Ravandi Blvd

City

Kashan

Province

Isfahan

Postal code

87159/81151

Phone

+98 31 5554 0026

Fax

+98 31 5554 8900

Email

beheshtihospital@kaums.ac.ir

Web page address

<http://beheshti.kaums.ac.ir/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Hamidreza Banafsheh

Street address

Kashan University of Medical Sciences, Ghotbe Ravandi Boulevard

City

Kashan

Province

Isfahan

Postal code

87159/81151

Phone

+98 31 5554 2999

Fax

Email

banafshe57@hotmail.com

Web page address

Grant name

Grant code / Reference number

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

No

Title of funding source

Vice chancellor for research, Kashan 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

+98 31 5554 8900

Email

kamalesalatmanesh@kaums.ac.ir

Web page address

<http://beheshti.kaums.ac.ir/>

Person responsible for general inquiries**Contact****Name of organization / entity**

Kashan University of Medical Sciences

Full name of responsible person

Kamal Esalatmanesh

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Rheumatology

Street address

Shahid Beheshti Hospital, Qotb-e Ravandi Blvd

City

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Web page address

<http://beheshti.kaums.ac.ir/>

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Kashan University of Medical Sciences

Full name of responsible person

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Latest degree

Subspecialist

Other areas of specialty/work

Rheumatology

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Fax**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