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

Isfehan

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
Isfehan
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
Isfehan
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

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
Kashan
Province
Isfehan
Postal code
87159/81151
Phone
+98 31 5554 0026
Fax
+98 31 5554 8900
Email
kamalesalatmanesh@kaums.ac.ir
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
Kamal Esalatmanesh
Position
Associate professor
Latest degree
Subspecialist
Other areas of specialty/work
Rheumatology
Street address
Shahid Beheshti Hospital, Qotb-e Ravandi Blvd
City
Kashan
Province
Isfehan
Postal code
87159/81151
Phone
+98 31 5554 0026
Fax
+98 31 5554 8900
Email
kamalesalatmanesh@kaums.ac.ir
Web page address
http://beheshti.kaums.ac.ir/

Person responsible for updating data

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
Kashan
Province
Isfehan
Postal code
87159/81151
Phone
+98 31 5554 0026
Fax
+98 31 5554 8900
Email
kamalesalatmanesh@kaums.ac.ir
Web page address
http://beheshti.kaums.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