Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

Investigation of the effect of curcumin supplementation on clinical status, inflammatory factors, oxidative stress biomarkers in patients with rheumatoid arthritis

Protocol summary

Study aim

Determining the effect of curcumin supplementation on clinical symptoms, inflammatory factors, oxidative stress biomarkers in Rheumatoid arthritis patients

Design

In this clinical trial (phase 3), two parallel, two-blind, randomized groups with two groups as Control and Intervention (30 people in each group) were first selected as available and then randomly selected in each group. They are selected based on body mass index and weight

Settings and conduct

This study was conducted in Rheumatoid arthritis patients referred to the Rheumatology clinic of Shahid Beheshti Hospital in Kashan. In this study, patients in both Intervention and Control groups receive standard treatment. In the intervention group, Curcumin produced by Dinah Pharmaceutical Company, with a dose of 500 mg, 1 tablet daily for 12 weeks, in addition to standard treatment and in the control group Placebo is used in addition to standard treatment. Placebo and Curcumin are both in the same form, same weight and same packaging, which is written by the researcher on the back of the package, and the doctor and the patient do not know whether it is a drug or a placebo.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with Rheumatoid arthritis based on diagnostic criteria Age 20-70 years No smoking. Exclusion criteria: Reluctance to cooperate Hypothyroidism or hyperthyroidism Consumption of any type of supplement (Vitamins, salts, etc.) by the patient during the last 3 months Having any acute and active infection.

Intervention groups

Intervention group: Taking Curcumin alongside standard treatment Control group: receiving a Placebo alongside the standard treatment

Main outcome variables

Severity of clinical symptoms before and after treatment based on Disease Activity Score 28 and Visual Analog Scale; plasma total antioxidant; plasma malondialdehyde; serum Hs-CRP

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20101014004934N3**
Registration date: **2023-11-27, 1402/09/06**
Registration timing: **registered_while_recruiting**

Last update: **2023-11-27, 1402/09/06**
Update count: **0**

Registration date

2023-11-27, 1402/09/06

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

2023-11-22, 1402/09/01

Expected recruitment end date

2024-03-19, 1402/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the effect of curcumin supplementation on clinical status, inflammatory factors, oxidative stress biomarkers in patients with rheumatoid arthritis

Public title

Investigating the effect of curcumin in rheumatoid arthritis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with rheumatoid arthritis based on diagnostic criteria Age 20-70 years No smoking

Exclusion criteria:

Reluctance to cooperate Hypothyroidism or hyperthyroidism Consumption of any type of supplement (vitamins, salts, etc.) by the patient during the last 3 months Having any acute and active infection

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, initial sampling is done by the 'available' method from the rheumatology clinic of Beheshti Hospital among the patients who come for treatment. The way of randomization is that rheumatoid arthritis patients are placed in separate classes based on two criteria: BMI (BMI < 30 and BMI ≥ 30) and age (> 45 and ≤ 45) and then are randomly assigned to one of the two groups. Curcumin or placebo (containing starch) are added as supplements. Randomization is done using Stat Trek software and based on the random number table method.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient and the attending physician are not aware of the fact that the patient is receiving a placebo or curcumin supplement.

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

Shahid Beheshti Hospital, Hekmat 56 ave, Qutb Rawandi Blvd, Kashan

City

Kashan

Province

Isfehan

Postal code

8715973447

Approval date

2023-10-22, 1402/07/30

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1402.180

Health conditions studied

1

Description of health condition studied

Rheumatoid Arthritis

ICD-10 code

M06.9

ICD-10 code description

Rheumatoid arthritis, unspecified

Primary outcomes

1

Description

Severity of clinical symptoms before and after treatment

Timepoint

Before the start of the intervention and twelve weeks later

Method of measurement

Based on Disease Activity Score 28 (DAS28) and Visual Analog Scale (VAS)

2

Description

Total plasma antioxidant

Timepoint

Before the start of the intervention and twelve weeks later

Method of measurement

Antioxidant capacity of plasma is determined by ELISA method

3

Description
Plasma malondialdehyde
Timepoint
Before the start of the intervention and twelve weeks later
Method of measurement
Determination of malondialdehyde is done by ELISA method

4

Description
Serum Hs-CRP
Timepoint
Before the start of the intervention and twelve weeks later
Method of measurement
Serum hs-CRP is performed using an ELISA device (immunoassay method).

Secondary outcomes

empty

Intervention groups

1

Description
The Intervention group: includes 30 Rheumatoid arthritis patients aged 20 to 70 referring to the Rheumatology clinic of Shahid Beheshti Hospital in Kashan (out of 60 Rheumatoid arthritis patients randomly selected), who are supplemented with Curcumin produced by Dineh Pharmaceutical Company, with a dose of 500 mg, 1 daily for 12 weeks in addition to the standard treatment of Rheumatoid arthritis.
Category
Treatment - Drugs

2

Description
Control group: includes 30 Rheumatoid arthritis patients aged 20 to 70 referring to the Rheumatology clinic of Shahid Beheshti Hospital in Kashan (out of sixty Rheumatoid arthritis patients randomly selected), who received a Placebo pill (Starch: containing 505 mg of Maltodextrin) with the appearance characteristics Same as 505 mg Curcumin supplement, 1 daily for 12 weeks in addition to standard treatment of Rheumatoid arthritis.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Rheumatology Clinic of Shahid Beheshti Hospital, Kashan
Full name of responsible person
Kamal Esalatmanesh
Street address
Shahid Beheshti Hospital, Hekmat 56 ave, Qutb Rawandi Blvd, Kashan
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8715973447
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beheshtihospital@kaums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Gholam Ali Hamidi
Street address
Research Vice-Chancellor, Kashan University of Medical Sciences, 5th kilometer of Qutb Rawandi Blvd, Kashan
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8715988141
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research@kaums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
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
Professor
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
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Shahid Beheshti Hospital, Hekmat 56 ave, Qutb Rawandi Blvd, Kashan
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Person responsible for scientific inquiries

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Person responsible for updating data

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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