

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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

Isfahan

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

City

Kashan

Province

Isfahan

Postal code

8715973447

Phone

+98 31 5500 9999

Email

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

City

Kashan

Province

Isfahan

Postal code

8715988141

Phone

+98 31 5558 9399

Email

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

Street address

Shahid Beheshti Hospital, Hekmat 56 ave, Qutb

Rawandi Blvd, Kashan

City

Kashan

Province

Isfahan

Postal code

8715973447

Phone

+98 31 5500 9999

Email

Kamalesalatmanesh@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

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

Street address

Shahid Beheshti Hospital, Hekmat 56 ave, Qutb

Rawandi Blvd, Kashan

City

Kashan

Province

Isfahan

Postal code

8715973447

Phone

+98 31 5500 9999

Email

Kamalesalatmanesh@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

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

Street address

Shahid Beheshti Hospital, Hekmat 56 ave, Qutb

Rawandi Blvd, Kashan

City

Kashan

Province

Isfahan

Postal code

8715973447

Phone

+98 31 5500 9999

Email

Kamalesalatmanesh@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