Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of curcumin-piperine supplementation on inflammatory factors and clinical signs in patients with rheumatoid arthritis: a double-blind clinical trial study

Protocol summary

Study aim

The effect of curcumin-piperine supplementation on inflammatory factors and clinical signs in patients with rheumatoid arthritis

Design

This study is a clinical trial with a control and randomized parallel double-blind group, in which 54 patients with rheumatoid arthritis will be divided into two groups receiving curcumin-piperine supplement (n = 27) and placebo (n = 27).

Settings and conduct

In this study, people with rheumatoid arthritis will be admitted to Al-Zahra Hospital. Random allocation will be done using a random number table. Entry of individuals and assignment of each person to one of the two groups will be done by the relevant specialist. Curcumin-piperine supplement and placebo will be packaged in similar boxes and the researcher and patients will not be informed of the contents of the packages until the end of the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Willingness to participate in the study, age 30-70 years, completing informed consent.Rheumatoid arthritis According to the rheumatologist Inclusion criteria: Pregnancy and lactation Smoking Underlying diseases, weight loss and bariatric surgery in a recent years, lack of special diet and herbal supplements

Intervention groups

1) Intervention group (n = 27) daily one capsule containing curcumin piperine (containing 500 mg of curcumin extract and 5 mg of piperine 2) control group (n = 27) daily placebo capsule (505 mg of maltodextrin) with diet and activity recommendations.

Main outcome variables

Clinical signs, inflammation indices such as quantitative CRP and ESR, and oxidative stress factors such as Total antioxidant capacity (TAC), Superoxide dismutase (SOD), Malondialdehyde (MDA), Rheumatoid factor (RF)

General information

Reason for update

To enhance the statistical power of the study, we propose increasing the sample size to 54 participants and distinguishing between primary and secondary outcomes.

Acronym

IRCT registration information

IRCT registration number: **IRCT20121216011763N53**
Registration date: **2021-08-10, 1400/05/19**
Registration timing: **prospective**

Last update: **2025-07-08, 1404/04/17**
Update count: **2**

Registration date

2021-08-10, 1400/05/19

Registrant information

Name
Gholamreza Askari
Name of organization / entity
Isfahan University of Medical Sciences
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Iran (Islamic Republic of)
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+98 31 1792 2110
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-22, 1400/10/01

Expected recruitment end date
2022-08-22, 1401/05/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of curcumin-piperine supplementation on inflammatory factors and clinical signs in patients with rheumatoid arthritis: a double-blind clinical trial study

Public title
Evaluation of the effect of curcumin-piperine in the treatment of rheumatoid arthritis
Purpose
Basic scienece
Inclusion/Exclusion criteria
Inclusion criteria:
Willingness to participate in the study Age: 30-70 years Complete informed consent Rheumatoid arthritis according to the rheumatologist according to the criteria of the American College of Rheumatology 2010 Disease activity score higher than 5.1 and total soft joint count (TJC) and swollen joint count (SJC) higher than 8
Exclusion criteria:
Pregnancy and lactation Smoking Heart, lung, kidney, hepatitis, cirrhosis, biliary and immune system disorders, hypertension, uncontrolled diabetes, hypothyroidism, Cushing's syndrome Weight loss and bariatric surgery in the last year. Lack of following a special diet and herbal supplements
Age
From **30 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **54**
Randomization (investigator's opinion)
Randomized
Randomization description
Participants will be divided into intervention and control groups using block classified randomization. The following authoritative site will be used to allocate the intervention in the above-mentioned manner. https://www.sealedenvelope.com/simple-randomiser/v1/lists In this way, people are randomly divided into two groups of intervention and control using quadruple blocks based on age and sex. It is noteworthy that participants and outcome assessors will not be aware of patient grouping and will be blind to it.
Blinding (investigator's opinion)
Double blinded
Blinding description
In order to conduct this research in a double-blind manner, before starting the study, the total capsules are coded in A and B by a person other than the researcher, so that both groups do not know the type of capsules received by both groups. To keep track of people in the study groups using the capsules, they will be contacted weekly by phone or text message and will be reminded of the capsule use. To check patients' compliance, curcumin and placebo capsules are given to them on a monthly basis and they are asked to deliver the previous capsule pack so that we can give them the new pack. Capsule use is also reminded and evaluated by weekly phone calls and text messages.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committe of Isfahan University of Medical Sciences
Street address
Isfahan University of Medical Sciences, Hezar Jerib Avenue
City
ISFAHAN
Province
Isfehan
Postal code
8174673461
Approval date
2021-04-21, 1400/02/01
Ethics committee reference number
IR.MUI.RESEARCH.REC.1400.068

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
Total antioxidant capacity (TAC)
Timepoint
Beginning and end of the study
Method of measurement
Colorimetric method

2

Description
C-reactive protein (CRP)
Timepoint
Beginning and end of the study
Method of measurement
Colorimetric analysis method and by autoanalyzer

3

Description
ESR
Timepoint
Beginning and end of the study
Method of measurement
Enzymatic method

4

Description
Clinical signs
Timepoint
Beginning and end of the study
Method of measurement
Diagnosis by a specialist and validated questionnaires

5

Description
Superoxide dismutase (SOD)
Timepoint
Beginning and end of the study
Method of measurement
Colorimetric method

6

Description
Malondialdehyde (MDA)
Timepoint
Beginning and end of the study
Method of measurement
Colorimetric method

7

Description
Rheumatoid factor (RF)
Timepoint
Beginning and end of the study
Method of measurement
ELISA

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Take one capsule containing curcumin piperine daily (containing 500 mg curcumin extract and 5 mg piperine) for 12 weeks. They will also receive diet and exercise advice.Dietary recommendations mainly include emphasizing the consumption of foods containing antioxidants in order to reduce inflammation and prevent the increase of inflammation, such as the cabbage and berry family. It is also recommended that people do a little physical activity that does not increase the problems caused by rheumatoid arthritis and help improve the condition.
Category
Treatment - Drugs

2

Description
Control group: They will receive one placebo capsule (505 mg of maltodextrin) daily with diet and exercise recommendations. Dietary recommendations mainly include emphasizing the consumption of foods containing antioxidants in order to reduce inflammation and prevent the increase of inflammation, such as the cabbage and berry family. It is also recommended that people do a little physical activity that does not increase the problems caused by rheumatoid arthritis and help improve the condition.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Zahra hospital
Full name of responsible person
Ghulam Reza Askari
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Mohammad Bagherniya
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

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Associate professor
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

The collected deidentified for the primary outcome measure only will be shared.

When the data will become available and for how long

12 months after publication

To whom data/document is available

Available for people working in academic institutions

Under which criteria data/document could be used

To conduct similar studies

From where data/document is obtainable

askari@mui.ac.ir

What processes are involved for a request to access data/document

The data will send as soon as possible, after receiving the request.

Comments