Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

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

Design
This trial is a randomized double blinded study. Randomization is done by Excel software on 60 patients.

Settings and conduct
This double-blind study was performed on patients with rheumatoid arthritis referred to Al-Zahra Hospital clinic. The intervention group received curcumin-piperine supplement for 12 weeks and the control group received maltodextrin supplement for 12 weeks. In this study, blindness is performed on researchers and patients who participated in the project

Participants/Inclusion and exclusion criteria
Inclusion criteria: Willingness to participate in the study Age 20-60 years Rheumatoid arthritis according to the rheumatologist according to the American College of Rheumatology 2010, the disease activity score is higher than 1.5 and the total soft joint count (TJC) and swollen joint count (SJC) is higher than 8 (32). Inclusion criteria: Pregnancy and lactation Smoking Heart, lung, kidney, hepatitis, cirrhosis, biliary and immune system disorders, hypertension, diabetes, hypothyroidism, Cushing's syndrome Weight loss and bariatric surgery in the last year.

Intervention groups
Group 1) Patients who receive one placebo capsule daily for 12 weeks, each capsule containing 500 mg of maltodextrin per day. (30 patients) Group 2) Patients who receive one 500 mg capsule per day containing 500 mg curcumin and 5 mg piperine daily for 12 weeks (30 patients)

Main outcome variables
Clinical signs in patients with rheumatoid arthritis

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120701010149N3**
Registration date: **2021-05-01, 1400/02/11**
Registration timing: **prospective**

Last update: **2021-05-01, 1400/02/11**
Update count: **0**

Registration date
2021-05-01, 1400/02/11

Registrant information

Name
peyman mottaghi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 3229 3863

Email address
motaghi@med.mui.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-05-04, 1400/02/14

Expected recruitment end date
2022-05-04, 1401/02/14

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of curcumin-piperine supplementation on anthropometric indices and clinical signs in patients with rheumatoid arthritis A double-blind clinical trial study

Public title
The effect of curcumin on rheumatoid arthritis

Purpose
Basic scienece

Inclusion/Exclusion criteria

Inclusion criteria:
Willingness to participate in the study Age 20-60 years Rheumatoid arthritis according to the rheumatologist according to the American College of Rheumatology 2010, the disease activity score is higher than 1/5 and the total soft joint count (TJC) and swollen joint count (SJC) is higher than 8.

Exclusion criteria:
Pregnancy and lactation Smoking Heart, lung and kidney disease, hepatitis, cirrhosis, biliary and immune system disorders, hypertension, diabetes, hypothyroidism, Cushing's syndrome

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
They will be randomly divided into one of two groups of intervention and placebo and will be studied for 12 weeks. The intervention group will receive a daily capsule containing curcumin piperine (containing 500 mg of curcumin extract and 5 mg of piperine) and the control group will receive a daily placebo capsule (500 mg of maltodextrin) with diet and exercise recommendations; The recommendations are the same in both groups.

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 track that individuals in the study groups use the capsules

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Isfahan University of Medical Sciences

Street address
Azadi Square, Hezar Jarib St., Isfahan University of Medical Sciences

City
Isfahan

Province
Isfehan

Postal code
۸۱۷۴۶۷۳۴۶۱

Approval date
2021-01-24, 1399/11/05

Ethics committee reference number
IR.MUI.MED.REC.1399.975

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
Symptoms

Timepoint
Beginning and end of the study

Method of measurement
Symptoms will be measured using the Disease Activity Score of 28 joints (DAS - 28). Soft joint count (TJC) and swollen joint count (SJC) are determined by a rheumatologist.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients receiving one 500 mg capsule per day of curcumin-piperine (500 mg

curcumin-5 mg piperine) per day for 12 weeks (30 patients)

Category

Treatment - Drugs

2

Description

Control group: Patients receiving 1 placebo capsule containing 500 mg maltodextrin daily for 12 weeks (30 patients)

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Hospital

Full name of responsible person

peiman motaghi

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Azadi Square, Hezar Jarib St., Isfahan University of Medical Sciences

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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mtav9614@gmail.com

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

peiman motaghi

Position

دانشیار

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

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Position

Associate Professor

Latest degree

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Other areas of specialty/work

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Latest degree

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Other areas of specialty/work

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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

Not applicable

Title and more details about the data/document

All data can be shared at the request of individuals

When the data will become available and for how long

Six months after publishing the results.

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

Scientific uses

From where data/document is obtainable

By sending an email to the following address that belongs to the executor of the project: motaghi@med.mui.ac.ir

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

Clear request on the site to access the data by the individual and then review the request by the research assistant within 2 weeks and then allow access to the data.

Comments