

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effects of curcumin supplementation on some metabolic and clinical parameters in women with rheumatoid arthritis

Protocol summary

Study aim

Determining the effect of curcumin supplementation on some metabolic and clinical parameters in women with rheumatoid arthritis

Design

Samples were selected using available methods and randomly assigned random blocks of 8 volumes to the study groups. A random sequence is generated using the STATA14 software. During the random assignment, individuals in the groups will be classified according to menopausal status, age and BMI variables

Settings and conduct

The aim of this study is to investigate the effects of curcumin supplementation on some metabolic and clinical parameters in women with rheumatoid arthritis that referred to Rheumatology Clinic of Imam Reza Hospital in Tabriz. 24-hour dietary recall questionnaire for 3 days, anthropometric indices, IPAQ, DAS28 will be completed for each individual. At the beginning and end of the intervention, 8 ml venous blood samples will be taken and kept at -70° until testing

Participants/Inclusion and exclusion criteria

include criteria: The age range of 20-70 years in women, Diagnosis of RA according to ACR, Moderate RA (disease activity score 1.5-3.2), No infectious disease at least two weeks before study, Body mass index less than 40 kilograms per square meters, willingness to participate in the study. exclude criteria: Pregnant or lactating women and those under hormone therapy or use of oral contraceptives, suffering from cardiovascular disease, liver and kidney failure and inflammatory disease, diabetes and hypertension, Changes in medications during the study, use of curcumin supplements and any antioxidant supplements in the last 2 months and during the study, weight loss diet, smoking.

Intervention groups

group 1 receiving curcumin (1 capsule 500 mg), group 2 placebo group (1 capsule 500 mg placebo)

Main outcome variables

serum level of lipid profile, glycemic, hs-CRP, ESR, visfatin and Disease Activity Score28 (DAS28)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100408003664N24**

Registration date: **2020-01-06, 1398/10/16**

Registration timing: **registered_while_recruiting**

Last update: **2021-12-23, 1400/10/02**

Update count: **1**

Registration date

2020-01-06, 1398/10/16

Registrant information

Name

Maryam Rafraf

Name of organization / entity

Tabriz University Of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 41 1335 7580

Email address

rafrafm@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-08, 1398/09/17

Expected recruitment end date

2020-03-07, 1398/12/17

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of curcumin supplementation on some metabolic and clinical parameters in women with rheumatoid arthritis

Public title

The effects of curcumin supplementation in the treatment of rheumatoid arthritis disease

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

The age range of 20-70 years in women Diagnosis of RA based on American College Rheumatology criteria and duration of more than one year Moderate RA (disease activity score 1.5-3.2) No infectious disease at least two weeks before study Body mass index less than 40 kilograms per square meters willingness to participate in the study.

Exclusion criteria:

Pregnant or lactating women those under hormone therapy or use of oral contraceptives suffering from cardiovascular disease, liver and kidney failure and inflammatory disease, diabetes and hypertension use of lipid and glycemic lower drugs and anticoagulant drugs Changes in medications during the study use of curcumin supplements and any antioxidant supplements in the last 2 months and during the study weight loss diet smoking

Age

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

Gender

Female

Phase

2

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples were selected using available methods and randomly assigned random blocks of 8 volumes to the study groups. A random sequence is generated using the STATA14 software. During the random assignment, individuals in the groups will be classified according to menopausal status, age and BMI variables.

Blinding (investigator's opinion)

Double blinded

Blinding description

The placebo and supplement will be packed in the same number in similar packages. The method of blindness will be that the supplements and placebo will be delivered to the participants by someone other than the researcher, and the researcher will remain unaware until 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 Tabriz University of Medical Science

Street address

Tabriz University of Medical Science, Attar Neishabouri Avenue, Golgasht street, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5138663134

Approval date

2019-12-25, 1398/10/04

Ethics committee reference number

IR.TBZMED.REC.1398.1005

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**

serum level of hs-CRP

Timepoint

Before the intervention and 8 weeks after starting

Method of measurement

ELISA

2**Description**

Disease Activity Score28

Timepoint

Before the intervention and 8 weeks after starting

Method of measurement

3

Description

serum level of visfatin

Timepoint

Before the intervention and 8 weeks after starting

Method of measurement

ELISA

4

Description

serum level of ESR

Timepoint

Before the intervention and 8 weeks after starting

Method of measurement

Westergren

5

Description

Triglyceride

Timepoint

Before the intervention and 8 weeks after starting

Method of measurement

Enzymatic method

6

Description

Total cholesterol

Timepoint

Before the intervention and 8 weeks after starting

Method of measurement

Enzymatic method

7

Description

HDL-C

Timepoint

Before the intervention and 8 weeks after starting

Method of measurement

Enzymatic method

8

Description

LDL-C

Timepoint

Before the intervention and 8 weeks after starting

Method of measurement

Freidewald formula

9

Description

Fasting blood sugar

Timepoint

Before the intervention and 8 weeks after starting

Method of measurement

Enzymatic method

10

Description

Insulin

Timepoint

Before the intervention and 8 weeks after starting

Method of measurement

ELISA

11

Description

Insulin resistance

Timepoint

Before the intervention and 8 weeks after starting

Method of measurement

formula

12

Description

Total antioxidant capacity

Timepoint

Before the intervention and 8 weeks after starting

Method of measurement

Spectrophotometry

13

Description

Malondialdehyde

Timepoint

Before the intervention and 8 weeks after starting

Method of measurement

Spectrophotometry

Secondary outcomes

1

Description

Anthropometric measurements (BMI, WHR, WC)

Timepoint

Baseline and 8 weeks after the intervention

Method of measurement

Secca scale, non stretch meter

2

Description

Energy and nutrient intake

Timepoint

Baseline and 8 weeks after the intervention

Method of measurement

24-hour dietary recall questionnaire for 3 days (two on week days and one on a weekend or holiday)

3

Description

Physical activity

Timepoint

Baseline and 8 weeks after the intervention

Method of measurement

International Assessment of Physical Activity (IPAQ) questionnaire

Intervention groups

1

Description

Intervention group: 500 mg/day curcumin of karen company (1 capsule of 500 mg) after lunch for 2 month

Category

Treatment - Drugs

2

Description

Control group: 500 mg/day placebo(1 capsule of 500mg containing starch flour) after lunch for 2 month

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Rheumatology Clinic of Imam Reza Hospital in Tabriz

Full name of responsible person

Fateme Pourhabibi

Street address

Tabriz, Golgasht st, Imam Reza Hospital

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5166614711

Phone

+98 13 3360 5852

Email

Fatemephz1214@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr.Alireza Ostadrahimi

Street address

Faculty of Nutrition, Tabriz University of Medical Sciences, Golgasht street

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Fateme Pourhabibi

Position

MSC student in Nutrition

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

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Person responsible for updating data**Contact****Name of organization / entity**

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Full name of responsible person

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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