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 the 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

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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

Disease Activity Score 28 Questionnaire

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
City
Tabriz
Province
East Azarbaijan
Postal code
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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Tabriz
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5166614711
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+98 41 3336 3430
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nut-rc@tbzmed.ac.ir
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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Health and Nutrition school, Attare Neishabouri Avenue, Golgasht street
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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