

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effect of curcumin supplementation on disease activity, inflammatory factors and oxidative stress in patients with Systemic Lupus Erythematosus

Protocol summary

Study aim

Determining the effect of curcumin supplementation on disease activity, inflammatory factors and oxidative stress in patients with SLE

Design

Randomized, Placebo-Controlled, Double-Blind, Parallel-Group, Phase 3 Clinical Trial on 66 patients. A Randomized block design and random allocation software (RAS) will be used for randomization.

Settings and conduct

The present study will be conducted on 66 patients with Systemic lupus erythematosus from Sayad Shirazi Rheumatology Clinic in Gorgan. Subjects will be randomly allocated in curcumin and placebo groups. At the beginning of the study, each volunteer will complete a general questionnaire, disease activity questionnaire and a 3-day food record. Blood samples (10 cc) will be collected from each patient for measurement of study outcomes. Then curcumin group will receive two 500 mg curcumin capsules daily for 10 weeks and the placebo group will receive two placebo capsules daily for the same period. Evaluation of dietary intakes and blood sampling to measure biochemical parameters will be repeated at the end of the intervention period for both groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age between 18 and 60 years old, no history of gallstones, not following a special diet, not using anticoagulant drugs Exclusion criteria: pregnancy and lactation, change in type and dose of drugs, following a special diet during the study, starting to take any dietary supplements during the study

Intervention groups

The curcumin group will receive two 500 mg curcumin capsules daily for 10 weeks. The placebo group will receive two placebo capsules daily for 10 weeks.

Main outcome variables

High-sensitivity C-reactive protein, erythrocyte sedimentation rate, C3 complement, C4 complement, total complement, anti-double stranded DNA antibody, interleukin-6, malondialdehyde, total antioxidant capacity, protein carbonyl

General information

Reason for update

Due to remaining serum samples, we decided to measure other variables to reach more comprehensive results.

Acronym

IRCT registration information

IRCT registration number: **IRCT20210425051077N1**

Registration date: **2021-09-12, 1400/06/21**

Registration timing: **registered_while_recruiting**

Last update: **2023-09-26, 1402/07/04**

Update count: **1**

Registration date

2021-09-12, 1400/06/21

Registrant information

Name

Elahe Mohammadi

Name of organization / entity

Khalkhal University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 45 3242 6801

Email address

e.mohamadi52@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-23, 1400/05/01

Expected recruitment end date

2021-10-23, 1400/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of curcumin supplementation on disease activity, inflammatory factors and oxidative stress in patients with Systemic Lupus Erythematosus

Public title

Effect of curcumin supplementation in patients with lupus

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Not using any nutritional supplements within 2 months before the beginning of the study except calcium-vitamin D supplement No history of gallstones Not following a special diet Not using anticoagulant drugs Not having Coronavirus Disease Age between 18 and 60 years old

Exclusion criteria:

Pregnancy and lactation Change in type and dose of drugs Following a special diet during the study Starting to take any dietary supplements during the study Having Coronavirus Disease

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be allocated in curcumin or placebo group using a randomized block design and the random allocation software (RAS,link:<https://bmcmmedresmethodol.biomedcentral.com/articles/10.1186/1471-2288-4-26>), with subjects matched in each block by sex, the category of medication (anti-malaria, corticosteroids and immunosuppressive drugs) and status of calcium-vitamin D intake (using or not using). To achieve blinding the volume of each block will be considered 4.

Blinding (investigator's opinion)

Double blinded

Blinding description

The supplement and placebo boxes will be coded by investigator as A and B. and then they will be distributed among the patients by one of the staff who had no clinical involvement in the study and information about the contents of the boxes.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Khalkhal University of Medical Sciences

Street address

Khalkhal University of Medical Sciences., Mozaffar Azizi St

City

Khalkhal

Province

Ardabil

Postal code

۵۶۸۱۷۶۱۳۵۱

Approval date

2021-07-15, 1400/04/24

Ethics committee reference number

IR.KHALUMS.REC.1399.019

Health conditions studied**1****Description of health condition studied**

Systemic lupus erythematosus

ICD-10 code

M32.9

ICD-10 code description

Systemic lupus erythematosus (SLE)

Primary outcomes**1****Description**

High-sensitivity C-reactive protein

Timepoint

At the beginning of the study and after 10 weeks intervention

Method of measurement

Standard kit

2

Description

Erythrocyte sedimentation rate

Timepoint

At the beginning of the study and after 10 weeks intervention

Method of measurement

Westergren method

3

Description

C3 complement

Timepoint

At the beginning of the study and after 10 weeks intervention

Method of measurement

Standard kit

4

Description

C4 complement

Timepoint

At the beginning of the study and after 10 weeks intervention

Method of measurement

Standard kit

5

Description

Total Complement

Timepoint

At the beginning of the study and after 10 weeks intervention

Method of measurement

Standard kit

6

Description

Anti double stranded DNA antibody

Timepoint

At the beginning of the study and after 10 weeks intervention

Method of measurement

ELISA kit

7

Description

Interleukin-6

Timepoint

At the beginning of the study and after 10 weeks intervention

Method of measurement

ELISA kit

8

Description

Malondialdehyde

Timepoint

At the beginning of the study and after 10 weeks intervention

Method of measurement

Standard kit

9

Description

Total antioxidant capacity

Timepoint

At the beginning of the study and after 10 weeks intervention

Method of measurement

Standard kit

10

Description

Protein carbonyl

Timepoint

At the beginning of the study and after 10 weeks intervention

Method of measurement

ELISA kit

11

Description

Disease activity

Timepoint

At the beginning of the study and after 10 weeks intervention

Method of measurement

Systemic Lupus Erythematosus Disease Activity Index 2000 Questionnaire

12

Description

Nitric oxide

Timepoint

At the beginning of the study and after 10 weeks intervention

Method of measurement

Standard kit

13

Description

8-isoprostane

Timepoint

At the beginning of the study and after 10 weeks intervention

Method of measurement

ELISA kit

14

Description

Matrix metalloproteinase 9

Timepoint

At the beginning of the study and after 10 weeks

intervention
Method of measurement
ELISA kit

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: curcumin group will receive two 500 mg curcumin capsules (Karen Co.) daily for 10 weeks

Category

Treatment - Drugs

2

Description

Control group: control group will receive two placebo capsules (Karen Co.) daily for 10 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Sayad Shirazi Hospital

Full name of responsible person

Zeinab Faramarzi

Street address

Sayyad Shirazi Blvd

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Gorgan

Province

Golestan

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49178 67439

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+98 17 3225 1502

Email

zefaramarzyp78@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research of Khalkhal University of Medical Sciences

Full name of responsible person

Esmaeil Mehraeen

Street address

Mozaffar Azizi

City

Khalkhal

Province

Ardabil

Postal code

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Phone

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es.mehraeen@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for Research of Khalkhal 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

Khalkhal University of Medical Sciences

Full name of responsible person

Elahe Mohammadi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

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

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

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

Khalkhal University of Medical Sciences

Full name of responsible person

Elahe Mohammadi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition