

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 May 2026

The effect of zinc supplementation on clinical symptoms, quality of life and its effect on inflammatory biomarkers and the expression of NF-kB, calprotectin, TLR-4 and TNF- α genes in patients with ulcerative colitis

Protocol summary

Study aim

Determining the effect of zinc supplementation on clinical symptoms, quality of life, and its effect on inflammatory biomarkers and expression of NF-kB, calprotectin, TLR-4, and TNF- α genes in patients with ulcerative colitis

Design

The randomized, double-blind, parallel-control clinical trial, phase 3, on 60 patients

Settings and conduct

In the field of clinical- at Rasoul Akram Hospital- after the definite diagnosis of ulcerative colitis, the questionnaires will be completed and the next day they will be sent to the laboratory for sampling and they will receive supplements.-The interviewer, the doctor and the patient will not be aware of the type of intervention.

Participants/Inclusion and exclusion criteria

Age 18 to 50 years - Body mass index 18.5 to 35 - Diagnosis of ulcerative colitis according to colonoscopy imaging and sample pathology - Mild to moderate severity active form of the disease - Absence of concomitant diseases such as malignant diseases and other inflammatory diseases - No recurrence of the disease in the last 3 months - no intestinal surgery - no use of zinc and other supplements during the last 2 months - no special diet - no use of infliximab, Adalimumab, high dose corticosteroids, NSAIDs - no pregnancy and breastfeeding

Intervention groups

Zinc gluconate in the intervention group and placebo in the control group

Main outcome variables

Primary outcome: clinical symptoms, secondary outcome: quality of life, inflammatory factors, expression of NF-kB, calprotectin, TLR-4, and TNF- α genes.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190710044172N1**

Registration date: **2022-11-30, 1401/09/09**

Registration timing: **prospective**

Last update: **2022-11-30, 1401/09/09**

Update count: **0**

Registration date

2022-11-30, 1401/09/09

Registrant information

Name

Masoumeh Khalighi Sikaroudi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 86701

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-22, 1401/10/01

Expected recruitment end date

2023-05-20, 1402/02/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of zinc supplementation on clinical symptoms, quality of life and its effect on inflammatory biomarkers and the expression of NF-kB, calprotectin, TLR-4 and TNF- α genes in patients with ulcerative colitis

Public title

zinc supplementation in ulcerative colitis

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Body mass index 18.5 to 35 Diagnosis of ulcerative colitis according to the patient's symptoms, tests and colonoscopy image and intestinal sample pathology Mild to moderate active form of the disease according to the Mayo questionnaire No change in clinical symptoms during the last week of entering the study Absence of concomitant diseases such as malignant diseases and other inflammatory diseases (cancer, kidney failure, heart failure, liver disorders, Wilson's, rheumatoid arthritis, diabetes, psoriasis, Behcet and other inflammatory and autoimmune diseases) No hospitalization and no medication changes during the last 3 months due to the severity of the disease Not having an acute disease (cold, corona and any other viral-bacterial-fungal disease) No intestinal surgery Not taking zinc supplements in the last 2 months Not taking supplements containing antioxidants - omega 3 - vitamin D - probiotic - vitamin E - vitamin A - multivitamin in the last two months

Exclusion criteria:

Use of infliximab, Adalimumab, high dose of corticosteroids (above 40 mg), NSAIDs pregnant and lactating women Taking contraceptives Implementation of special diet such as vegetarian diet, ketogenic diet and gluten-free diet

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

After selecting the patients, people are randomly assigned to two groups receiving zinc gluconate supplement and placebo. For randomization, permuted block randomization with 4 blocks (based on sex and BMI) will be used. The randomization will be individual. In order to apply concealment in the randomization process, unique codes will be used on the complementary boxes, and the desired code will be

generated by the software and will be done with the envelope-sealed method with a random sequence. As each person enters the study based on the generated sequence, the supplementary package in which the desired code is registered will be allocated to the person, and therefore, before choosing the person, no one will be aware of the type of treatment he will receive. Also, the interrogator and the attending physician will not be aware of the intervention.

Blinding (investigator's opinion)

Double blinded

Blinding description

In order to apply concealment (in a double-blind manner) in the randomization process, unique codes will be used on the complementary boxes, and the desired code is also generated by the software and by the envelope-in-package method with a random sequence will be done. As each person enters the study based on the generated sequence, the supplementary package in which the desired code is recorded will be assigned to the person, and therefore, before choosing the person, no one will be aware of the type of treatment he will receive. Also, the interrogator and the attending physician will not be aware of the intervention.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Tehran University of Medical Sciences

Street address

13th floor, Block A, Treatment and Medical Education, Central Headquarters of the Ministry of Health, Simai Iran St., between South Flamek and Zarafshan, Quds town (west)

City

Tehran

Province

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Postal code

1954719951

Approval date

2022-11-26, 1401/09/05

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1401.607

Health conditions studied

1

Description of health condition studied

Ulcerative Colitis

ICD-10 code

K51.9

ICD-10 code description

Ulcerative colitis, unspecified

Primary outcomes

1

Description

Clinical symptoms

Timepoint

At the beginning (before the start of the intervention) and at the end of the intervention (60 days after taking zinc or placebo)

Method of measurement

Mayo questionnaire

Secondary outcomes

1

Description

Quality of life

Timepoint

At the beginning (before the start of the intervention) and at the end of the intervention (60 days after taking zinc or placebo)

Method of measurement

Inflammatory Bowel Disease Quality of Life Short Questionnaire (IBDQ-9)

2

Description

Serum zinc level

Timepoint

At the beginning (before the start of the intervention) and at the end of the intervention (60 days after taking zinc or placebo)

Method of measurement

In blood serum sample using ELISA kit

3

Description

Erythrocyte sedimentation rate (ESR)

Timepoint

At the beginning (before the start of the intervention) and at the end of the intervention (60 days after taking zinc or placebo)

Method of measurement

In blood serum sample using ELISA kit

4

Description

C-reactive protein (CRP)

Timepoint

At the beginning (before the start of the intervention) and at the end of the intervention (60 days after taking zinc or placebo)

Method of measurement

In blood serum sample using ELISA kit

5

Description

Interleukin 17 (IL-17)

Timepoint

At the beginning (before the start of the intervention) and at the end of the intervention (60 days after taking zinc or placebo)

Method of measurement

In blood serum sample using ELISA kit

6

Description

Interleukin 6 (IL-6)

Timepoint

At the beginning (before the start of the intervention) and at the end of the intervention (60 days after taking zinc or placebo)

Method of measurement

In blood serum sample using ELISA kit

7

Description

Interleukin 10 (IL-10)

Timepoint

At the beginning (before the start of the intervention) and at the end of the intervention (60 days after taking zinc or placebo)

Method of measurement

In blood serum sample using ELISA kit

8

Description

Transforming growth factor beta (TGF- β)

Timepoint

At the beginning (before the start of the intervention) and at the end of the intervention (60 days after taking zinc or placebo)

Method of measurement

In blood serum sample using ELISA kit

9

Description

tumor necrosis factor alpha (TNF- α)

Timepoint

At the beginning (before the start of the intervention) and at the end of the intervention (60 days after taking zinc or placebo)

Method of measurement

Gene expression in PBMC samples

10

Description

Nuclear factor kappa-light-chain-enhancer of activated B cells (NF-κB)

Timepoint

At the beginning (before the start of the intervention) and at the end of the intervention (60 days after taking zinc or placebo)

Method of measurement

Gene expression in PBMC samples

11

Description

Calprotectin gene expression

Timepoint

At the beginning (before the start of the intervention) and at the end of the intervention (60 days after taking zinc or placebo)

Method of measurement

Gene expression in PBMC samples

12

Description

Toll-like receptor 4 (TLR-4)

Timepoint

At the beginning (before the start of the intervention) and at the end of the intervention (60 days after taking zinc or placebo)

Method of measurement

Gene expression in PBMC samples

Intervention groups

1

Description

Intervention group: Along with their medical drugs, including Mesalazine and Azaram, zinc gluconate oral supplement from Karen pharmaceutical company with 30 mg of zinc elemental and capsule filler (glycerol, gelatin and lecithin) is taken once a day for 60 days. Patients are given two cans containing 30 capsules each month. The first can will be delivered to the patient on the day of sampling and instructions will be given on how to use it.

Category

Treatment - Drugs

2

Description

Control group: Along with their medical drugs, such as Mesalazine and Azaram, the placebo oral supplement from Karen pharmaceutical company without any medicinal combination and filled with glycerol, gelatin, and lecithin is taken once daily for 60 days. Patients are given two cans containing 30 capsules each month. The first can will be delivered to the patient on the day of sampling and instructions will be given on how to use it.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoul-e-Akram Hospital

Full name of responsible person

Gholamreza mohammadi farsani

Street address

Rasoul-e-Akram Hospital, Maziar Mansouri Street, Sattar Khan Street

City

Tehran

Province

Tehran

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Phone

+98 21 86701

Email

mohammadigh53@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Gholamreza mohammadi farsani

Street address

No. 44, Hojat Dost St., Naderi St., Keshavarz Blvd.

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Masoumeh Khalighi Sikaroudi

Position

PhD Student

Latest degree

Master

Other areas of specialty/work

Nutrition

Street address

Rasoul-e-Akram Hospital, Maziar Mansouri Street,
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+98 21 8895 5975

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masoomehkhalthighi@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Masoumeh Khalighi Sikaroudi

Position

PhD Student

Latest degree

Master

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Masoumeh Khalighi Sikaroudi

Position

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Latest degree

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Other areas of specialty/work

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Email

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

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 analysis and results of the study will be published.
Items related to the personal information of patients will
not be published.

When the data will become available and for how long

The access period starts 6 months after the results are
published

To whom data/document is available

Patients with ulcerative colitis, nutritionists, physicians

Under which criteria data/document could be used

It will be available to people in the form of brochures,
articles, and training courses.

From where data/document is obtainable

Executive and project manager
masoomehkhalthighi@gmail.com

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

They can request information and documents by email

Comments