

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

zinc supplementation in patients with ulcerative colitis: effects on clinical symptoms, and inflammatory/anti-inflammatory cytokines affecting the immune system

Protocol summary

Study aim

1. Determining and comparing the severity of clinical symptoms between the two groups at the end of the study
2. Determining and comparing the quality of life between the two groups at the end of the study
3. Determination and comparison of inflammatory markers (IL-17, TNF- α , and IL-6 serum levels) between the two groups at the end of the study
4. Determination and comparison of anti-inflammatory markers (serum IL-10) between two groups at the end of the study

Design

Double-blind parallel controlled randomized clinical trial

Settings and conduct

Clinical - Rasool Akram Hospital - After the definitive diagnosis of ulcerative colitis, the questionnaires will be completed by the participants, and the next day they will be sent to the lab for sampling and they will receive the supplement on the same day. - 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 between 18.5 and 35 - Definitive diagnosis of ulcerative colitis according to the colonoscopy image and intestinal sample pathology - Mild to moderate 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 - Not taking supplements containing zinc and other supplements during the last 2 months - Not having a special diet - No use of infliximab, Sinora, high dose of corticosteroids (above 40 mg), NSAIDs - Not pregnant and breastfeeding

Intervention groups

Intervention with zinc gluconate in the intervention group
Intervention with placebo in the control group

Main outcome variables

Primary outcome: clinical symptoms
Secondary outcome: quality of life, inflammatory factors

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190712044182N3**

Registration date: **2022-09-18, 1401/06/27**

Registration timing: **prospective**

Last update: **2022-09-18, 1401/06/27**

Update count: **0**

Registration date

2022-09-18, 1401/06/27

Registrant information

Name

Mohsen Masoodi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6655 4790

Email address

masoodi.m@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-23, 1401/07/01

Expected recruitment end date

2023-09-23, 1402/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
zinc supplementation in patients with ulcerative colitis: effects on clinical symptoms, and inflammatory/anti-inflammatory cytokines affecting the immune system

Public title
"zinc supplementation"; "Ulcerative colitis"

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Body mass index between 18.5 and 35
Diagnosis of ulcerative colitis according to the patient's symptoms, tests and colonoscopy, and intestinal sample pathology
Mild to moderate active form of the disease according to the Mayo questionnaire
Absence of concomitant diseases
not taking supplements containing zinc during the last 2 months
No use of infliximab, Sinora, high dose of corticosteroids (above 40 mg), NSAIDs
Not pregnant or lactating
Not taking contraceptives
Exclusion criteria:

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

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
After selecting the patients, people are randomly assigned to two groups receiving a zinc gluconate supplement and a placebo. For randomization, permuted block randomization with 4 blocks and 2 blocks (based on age and BMI) will be used. The randomization unit 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 person evaluating the patient (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 (double-blind) 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 sealed envelope method. As each person enters the study based on the generated sequence, the supplementary package in which the desired code is recorded will be allocated to the person, and therefore, before choosing the person, no one will be not aware of the type of treatment he will receive. Also, the person evaluating the patient 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 Iran University of Medical Sciences
Street address
Iran University of Medical Sciences, Hemet Highway, next to Milad Tower, Tehran
City
Tehran
Province
Tehran
Postal code
۱۴۳۹۶۱۴۵۳۵

Approval date
2022-04-26, 1401/02/06

Ethics committee reference number
IR.IUMS.REC.1401.054

Health conditions studied

1

Description of health condition studied
ulcerative colitis disease
ICD-10 code
K51.9
ICD-10 code description
Ulcerative colitis, unspecified

Primary outcomes

1

Description

severity of clinical symptoms

Timepoint

At the baseline (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

Serum level of Interlukin-6

Timepoint

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

Method of measurement

In serum sample using ELISA kit

2

Description

Serum level of Interlukin-17

Timepoint

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

Method of measurement

In serum sample using ELISA kit

3

Description

Serum level of TNF- α

Timepoint

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

Method of measurement

In serum sample using ELISA kit

4

Description

Quality of life

Timepoint

At the baseline (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)

5

Description

Serum level of Interlukin-10

Timepoint

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

Method of measurement

In serum sample using ELISA kit

Intervention groups

1

Description

Intervention group: Patients take one daily zinc gluconate softgel from Dana Pharmaceutical Company with 40 mg of elemental zinc and capsule filler (glycerol, gelatin, and lecithin) along with their therapeutic medications, including Mesalazine and Azaram, for 60 days. Capsules are given to patients in two bottles containing 30 softgel in each of them. The first bottle 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: Patients take one daily placebo from Dana Pharmaceutical Company without any drug Compounds including zinc and a capsule filled with glycerol, gelatin, and lecithin along with their therapeutic medications, including Mesalazine and Azaram, for 60 days. Capsules are given to patients in two bottles containing 30 softgel in each of them. The first bottle 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

Mohsen Masoodi

Street address

Rasool Akram Hospital, Maziar Mansouri Street, Sattar Khan Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

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next to Milad Tower, Tehran

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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

Iran 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**

Iran University of Medical Sciences

Full name of responsible person

Mohsen Masoodi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Gholamreza Mohammadi Farsani

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for updating data

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

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Phone

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Email

masoomehkhaleghi@gmail.com

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

Undecided - It is not yet known if there will be 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

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

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 Correspondent
masoomekhkhligi@gmail.com

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

They can request information and documents by email

Comments