Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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
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Iran (Islamic Republic of)
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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)

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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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

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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
masoomehkhalighi@gmail.com

What processes are involved for a request to access data/document
They can request information and documents by email

Comments