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 Ḍiagnosis 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

۱۴۴۹۶۱۴۵۳۵

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

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Phone

+98 21 86701

Fax

+98 21 86701

Email

masoodi47@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Mohsen Masoodi
Street address
Iran University of Medical Sciences, Hemet Highway, next to Milad Tower, Tehran
City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
Phone
+98 21 86701
Email
info@iums.ac.ir
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
Street address
Sattar Khan Street, Maziar Mansouri Street, Rasool Akram Hospital
City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
Phone
+98 21 86701
Email
masoodi47@yahoo.com

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
Street address
No. 44, Hojat Dost St., Naderi St., Keshavarz Blvd., Tehran
City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
Phone
+98 21 8895 5975
Email
mohammadigh53@gmail.com

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
Street address
No. 44, Hojat Dost St., Naderi St., Keshavarz Blvd., Tehran
City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
Phone
+98 21 8895 5975
Email
masoomehkhalighi@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
masoomehkhalighi@gmail.com

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

Comments