Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of zinc supplementation separately and in combination with probiotics on inflammatory and oxidative stress indicators, the severity of gastrointestinal symptoms, mood disorders, quality of life and sleep in patients with irritable bowel syndrome: a double-blind randomized controlled clinical trial

Protocol summary

Study aim

To study the effects of zinc and probiotic on oxidative stress and inflammation, clinical, and mood variables in irritable bowel syndrome (IBS)

Design

84 patients will be randomly allocated to one of three groups. variables will be evaluated using valid questionnaires, tools, and lab tests.

Settings and conduct

The participants will be selected among IBS patients referred to the special clinic of Khorshid Hospital and Gastrointestinal Health Center of Al-Zahra Hospital in Isfahan, who were diagnosed by a gastroenterologist according to Rome IV criteria. Patients will be included in the study based on the inclusion criteria. Written informed consent will be obtained from all participants. Then, people will be randomly assigned to one of the 3 intervention groups. Anthropometric indicators will be measured and questionnaires will be completed. Arrangements will be made to perform the blood test on a certain day. Participants and outcome assessors will be blinded and unaware of the grouping of patients.

Participants/Inclusion and exclusion criteria

IBS patients aged 20 to 60 years with a body mass index of 18.5 to 40

Intervention groups

Group 1: zinc gluconate 20 mg and probiotic placebo
Group 2: 20 mg zinc gluconate and probiotic capsule
Group 3: zinc and probiotic placebos (microcrystalline cellulose) daily for 12 weeks

Main outcome variables

Serum zinc; tumor necrosis factor alpha; malondialdehyde; total oxidative status; total antioxidant capacity; Oxidative stress index; Superoxide dismutase; severity of gastrointestinal symptoms; depression; anxiety and stress; Quality of Life; sleep quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180818040827N5**
Registration date: **2024-01-29, 1402/11/09**
Registration timing: **prospective**

Last update: **2025-09-28, 1404/07/06**
Update count: **1**

Registration date

2024-01-29, 1402/11/09

Registrant information

Name
Reza Amnai
Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-07-22, 1403/05/01

Expected recruitment end date

2025-07-23, 1404/05/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of zinc supplementation separately and in combination with probiotics on inflammatory and oxidative stress indicators, the severity of gastrointestinal symptoms, mood disorders, quality of life and sleep in patients with irritable bowel syndrome: a double-blind randomized controlled clinical trial

Public title
Investigating the effect of zinc supplementation separately and in combination with probiotics in irritable bowel syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients who agree to participate in the study. Diagnosis of IBS by a gastroenterologist based on the Rome IV criteria Body mass index between 18.5 to 40
Exclusion criteria:
Regular consumption of probiotics and prebiotics products and supplements at least 2 months before the start of the study Taking zinc supplement in the last 6 months or following a special diet History of gastrointestinal surgery, celiac disease, infection or cancer of the gastrointestinal tract, inflammatory bowel diseases, rheumatism and other inflammatory diseases and malignancy Pregnant, breastfed, or hospitalized Allergy to the ingredients in the supplement Drinking alcohol, smoking Penicillamine use, regular use of anti-diarrheal or laxative drugs, antibiotics, use of drugs that alter digestive movements, use of drugs that increase bleeding from intestinal mucus such as warfarin, heparin Professional athletes All types of anemia
Age
From **20 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **84**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, 84 people will be included according to the included criteria. Participants will be divided into three groups (two intervention and one control group) using balanced (permuted) block randomization. Considering the three groups of the study, blocks of six will be considered, and the classification will be applied based on the gender variable. The reliable site (https://www.sealedenvelope.com/simple-randomiser/v1/lists) will be used to allocate the intervention in the mentioned way. It is worth noting that the participants and outcome assessors will not know about the grouping of patients and will be blind to it.
Blinding (investigator's opinion)
Double blinded
Blinding description
This study is a randomized double-blind clinical trial. Zinc supplement, probiotic supplement and their placebo will be packed in the same boxes in terms of appearance characteristics (color, shape, smell) and the researcher, patients, evaluators, and those responsible for collecting data will not be informed of the contents of the packages until the end of the study.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Schools of Pharmacy and Nutrition, Isfahan University of Medical Scien
Street address
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Province
Isfehan
Postal code
81746-73461
Approval date
2024-01-20, 1402/10/30
Ethics committee reference number
IR.MUI.PHANUT.REC.1402.079

Health conditions studied

1

Description of health condition studied
Irritable bowel syndrome
ICD-10 code
K58
ICD-10 code description
Irritable bowel syndrome

Primary outcomes

1

Description
Serum zinc level
Timepoint
Before and after the intervention
Method of measurement
Assay kit

2

Description
Total antioxidant capacity
Timepoint
Before and after the intervention
Method of measurement
Assay kit

3

Description
Gastrointestinal symptom severity
Timepoint
Before and after the intervention
Method of measurement
IBS Severity Score questionnaire

Secondary outcomes

1

Description
Tumor necrosis factor alpha
Timepoint
Before and after the intervention
Method of measurement
Assay kit

2

Description
Malondialdehyde
Timepoint
Before and after the intervention
Method of measurement
Assay kit

3

Description
Total oxidant status
Timepoint
Before and after the intervention
Method of measurement
Assay kit

4

Description
Oxidative stress index
Timepoint
Before and after the intervention
Method of measurement
Calculation

5

Description
Superoxide dismutase
Timepoint
Before and after the intervention
Method of measurement
Assay kit

6

Description
Depression, anxiety and stress
Timepoint
Before and after the intervention
Method of measurement
Depression Anxiety and Stress Scale 21

7

Description
quality of life
Timepoint
Before and after the intervention
Method of measurement
Irritable Bowel Syndrome Quality of Life questionnaire

8

Description
sleep quality
Timepoint
Before and after the intervention
Method of measurement
Pittsburgh Sleep Quality questionnaire

9

Description
Fatigue severity
Timepoint
Before and after the intervention
Method of measurement
Fatigue Severity Scale questionnaire

10

Description
Emotional patterns
Timepoint
Before and after the intervention
Method of measurement
Positive and Negative Affect Schedule questionnaire

11

Description
Anthropometric measurements
Timepoint
Before and after the intervention

Method of measurement
Omron BF-511 scale and tape measure

Intervention groups

1

Description
Intervention group: zinc gluconate 20 mg and probiotic placebo daily for 12 weeks
Category
Treatment - Other

2

Description
Intervention group: 20 mg zinc gluconate and probiotic capsule daily for 12 weeks
Category
Treatment - Other

3

Description
Control group: zinc and probiotic placebos (microcrystalline cellulose) daily for 12 weeks
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
special clinic of Khorshid Hospital
Full name of responsible person
Dr. Maryam Soheilipour
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2

Recruitment center
Name of recruitment center
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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
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Mahsa Rezazadegan
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Person responsible for updating data

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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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be 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
Major part of information will be available for population.
When the data will become available and for how long
12 months after publication
To whom data/document is available
Available for people working in academic institutions
Under which criteria data/document could be used
To conduct similar studies
From where data/document is obtainable
r_amani@nutr.mui.ac.ir
What processes are involved for a request to access data/document
The data will be sent as soon as possible, after receiving the request
Comments