Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effect of spirulina platensis supplementation on quality of life, severity of disease and serum total antioxidant capacity (TAC), manoldialdehyde (MDA) and zonulin in constipation-predominant Irritable bowel syndrome patients (IBS)

Protocol summary

Study aim
evaluating effect of spirulina platensis supplementation on quality of life, severity of disease and serum total antioxidant capacity, manoldialdehyde and zonulin in constipation-predominant Irritable bowel syndrome patients

Design
A parallel randomized double-blind (patients and investigator) placebo-controlled clinical trial. this study will be conducted on 60 patients. Permuted block randomization is used for randmization.

Settings and conduct
This study will be conducted in the clinic of gastrointestinal health center of Isfahan university of medical sciences. The intervention group will receive two tablet of spirulina (containing 500 mg of spirulina powder) daily after breakfast and dinner and the control group will receive two placebos daily, which are similar in shape, color, taste, and smell. Patients and researchers are not aware of how randomly assigned individuals are. At the beginning and end of the study, venous blood samples, anthropometric measurements, questionnaires related to IBS, demographic information and socio-economic status of patients will be measured and recorded.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age range of 18-50 years, patients diagnosed with irritable bowel syndrome through ROME IV criteria by a gastroenterologist; Exclusion criteria: Smoking, alcohol consumption, pregnancy or breastfeeding condition, taking antidepressants and anxiety medications, taking antioxidant and omega-3 supplements in the last three months, kidney, liver, thyroid and parathyroid, heart disease, cancer and gastrointestinal diseases other than IBS

Intervention groups
Patients will be assigned to receive spirulina supplements (n=30) and placebo (n=30)

Main outcome variables
quality of life, disease severity and serum zonulin level

General information

Reason for update
Considering the request from the journal where the protocol is currently under review, the disease subtype must be added to the title and inclusion criteria. Additionally, as the study has been completed, we request the addition of the sample collection end date to the registry.

Acronym

IRCT registration information
IRCT registration number: **IRCT20140208016529N8**
Registration date: **2023-04-25, 1402/02/05**
Registration timing: **prospective**

Last update: **2025-03-01, 1403/12/11**
Update count: **1**

Registration date
2023-04-25, 1402/02/05

Registrant information

Name
Mohammad hassan Entezari
Name of organization / entity
Isfahan university of medical sciences
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2023-06-06, 1402/03/16

Expected recruitment end date
2023-12-07, 1402/09/16

Actual recruitment start date
2023-08-25, 1402/06/03

Actual recruitment end date
2024-02-24, 1402/12/05

Trial completion date
2024-02-24, 1402/12/05

Scientific title
Effect of spirulina platensis supplementation on quality of life, severity of disease and serum total antioxidant capacity (TAC), manoldialdehyde (MDA) and zonulin in constipation-predominant Irritable bowel syndrome patients (IBS)

Public title
Effect of spirulina on Irritable bowel syndrome patients

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Ages range of 18-50 years patients diagnosed with irritable bowel syndrome through ROME IV criteria by a gastroenterologist

Exclusion criteria:
Smoking Alcohol consumption Pregnancy or breastfeeding condition Taking antidepressants and anxiety medications. Taking antioxidant and omega-3 supplements in the last three months Kidney, liver, thyroid and parathyroid, heart disease, cancer and gastrointestinal diseases other than IBS

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

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **60**
Actual sample size reached: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be performed by permuted block randomization method using size 4 blocks by Stata statistical software version 16. To conceal the random assignment process, 10-digit random codes are written on papers labels without a specific order and framework, which is the relevant treatment identification number, and only one person outside the design will be aware of the code. Labels will be affixed to drug packages in a random order list.

Blinding (investigator's opinion)
Double blinded

Blinding description
supplement and placebo are given to both groups in completely identical, unlabeled containers, which are prepared and coded in the same color and odor, by random allocation by the design partner, so neither patient is aware of the specific treatment and will not be informed until the end of the study. Also, the researcher evaluating the desired outcomes is unaware of the random allocation process and the type of treatment performed.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
ethics committee of Isfahan university of medical sciences

Street address
Hezarjrib Street

City
Isfehan

Province
Isfehan

Postal code
8174673461

Approval date
2023-02-28, 1401/12/09

Ethics committee reference number
IR.MUI.RESEARCH.REC.1401.370

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
Quality of life

Timepoint
At baseline and after 12 weeks

Method of measurement
Irritable bowel syndrome-quality of life- 34 (IBS-QOL-34)questionnaire

2

Description
Disease severity
Timepoint
At baseline and after 12 weeks
Method of measurement
Irritable bowel syndrome syndrome severity scale(IBS-SSS) questionnaire

3

Description
Serum zonulin level
Timepoint
At baseline and after 12 weeks
Method of measurement
Eliza kit

Secondary outcomes

1

Description
Total antioxidant capacity of serum
Timepoint
At baseline and after 12 weeks
Method of measurement
Colorimetric method

2

Description
Malonaldehyde
Timepoint
At baseline and after 12 weeks
Method of measurement
Colorimetric method

Intervention groups

1

Description
Intervention group: The intervention group will receive two capsule of spirulina (containing 500 mg of spirulina platensis powder) daily after breakfast for 12 weeks
Category
Treatment - Other

2

Description
Control group: The control group will receive two placebo daily that is similar in shape, color, taste, and smell to the supplement
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
clinic of gastrointestinal health center, Isfahan university of medical sciences
Full name of responsible person
Mohammad hasan Entezari
Street address
Hezarjarib street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Gholamreza Askari
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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
Mohammad hassan entezari

Position
professor

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

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School of Nutrition and Food Science, Isfahan University of Medical Sciences, Hezar Jarib Blvd

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
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Position
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Latest degree
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
It should be consulted with other members of group according to the university's policies

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
Undecided - It is not yet known if there will be a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable