

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 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

Country

Iran (Islamic Republic of)

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Email address

entezari@hlth.mui.ac.ir

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

Isfahan

Province

Isfahan

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 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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Isfahan

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81746-73461

Phone

+98 31 3792 3172

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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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askari@mui.ac.ir

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

Street address

School of Nutrition and Food Science, Isfahan
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Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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Professor

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