

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

Effect of Spirulina supplement (*Arthrospira platensis*) on disease activity indices, quality of life, mood, fatigue, serum antioxidant status and serum pentraxin 3 levels in patients with ulcerative colitis

Protocol summary

Study aim

The aim of study is evaluation the effects of spirulina supplementation on disease activity indices, quality of life, mood, fatigue, antioxidant status and serum pentraxin 3 levels (ptx3) in patients with ulcerative colitis

Design

Parallel double-blind (both patients and researchers) randomized controlled clinical trial. In this study 80 individuals will participate. Patients will be randomly divided into two groups. The first group of patients will receive Spirulina (*Arthrospira platensis*) 1 g daily and the second group will be age- and sex-matched colitis patients who will be selected as controls and receive placebo. All participants will receive two 500 mg capsules daily. Tests on participants' serum will include: ESR inflammatory markers, oxidative stress markers and serum pentraxin 3 levels.

Settings and conduct

This study was done in clinic.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients included in the study had mild or moderate levels of ulcerative colitis and were between 18 and 65 years of age. Exclusion criteria: Patients with severe ulcerative colitis or other chronic diseases. People during pregnancy or lactation. Smokers or alcohol users. Taking antidepressants and anxiety medications. Taking antioxidant and omega-3 supplements in the last three months.

Intervention groups

Patients will be assigned to receive spirulina supplements (n=40) and placebo (n=40)

Main outcome variables

ESR inflammatory markers, oxidative stress markers and serum pentraxin 3 levels.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191204045612N1**

Registration date: **2020-01-15, 1398/10/25**

Registration timing: **registered_while_recruiting**

Last update: **2021-04-05, 1400/01/16**

Update count: **1**

Registration date

2020-01-15, 1398/10/25

Registrant information

Name

Sajjad Moradi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3824 2314

Email address

smoradi@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-04, 1398/10/14

Expected recruitment end date

2021-01-03, 1399/10/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Spirulina supplement (*Arthrospira platensis*) on disease activity indices, quality of life, mood, fatigue, serum antioxidant status and serum pentraxin 3 levels in patients with ulcerative colitis

Public title

Effects of Spirulina supplementation on ulcerative colitis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with mild to moderate ulcerative colitis in the age range of 18 to 65 years

Exclusion criteria:

Patients with severe ulcerative colitis Individuals in pregnancy or breastfeeding condition. Taking antidepressants and anxiety medications. Taking antioxidant and omega-3 supplements in the last three months. Smokers or alcohol consumers. Patients with kidney, liver, thyroid and parathyroid, gastrointestinal and heart disease and cancer disease.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, a simple randomization method using random number table is used. This method first uses a random number table, which is a set of numbers that have no pattern or order and which is completely generated. The researcher divides these numbers randomly between the intervention and placebo groups. With the presence of clients, the researcher begins to read the numbers in the specified order. Each client receives its own number and is randomly assigned to either the intervention or the placebo group.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is a double-blind study. Given that the researcher and patient should not be aware of the contents of the capsules, the third person places the placebo and spirulina into identical and similar capsules and containers and encodes them randomly. Spirulina and placebo are then presented to the researcher with a code to disclose to the patient.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Vice-Chancellor in Research Affairs -Medical University of Isfahan

Street address

Hezar jarib

City

Isfahan

Province

Isfahan

Postal code

73461-81746

Approval date

2019-09-25, 1398/07/03

Ethics committee reference number

IR.MUI.RESEARCH.REC.1398.436

Health conditions studied

1

Description of health condition studied

Ulcerative colitis patients

ICD-10 code

K51.9

ICD-10 code description

Ulcerative colitis, unspecified

Primary outcomes

1

Description

Pentraxin 3

Timepoint

Before intervention and 8 weeks after initiation of Spirulina supplementation

Method of measurement

Eliza kit

2

Description

Total antioxidant capacity

Timepoint

Before intervention and 8 weeks after initiation of Spirulina supplementation

Method of measurement

Diagnostic kit

3

Description

Malondialdehyde

Timepoint
Before intervention and 8 weeks after initiation of Spirulina supplementation
Method of measurement
Diagnostic kit

4

Description
Superoxide dismutase
Timepoint
Before intervention and 8 weeks after initiation of Spirulina supplementation
Method of measurement
Diagnostic kit

5

Description
Erythrocyte Sedimentation Rate
Timepoint
Before intervention and 8 weeks after initiation of Spirulina supplementation
Method of measurement
Measurement of erythrocyte sedimentation rate

6

Description
Disease activity indices
Timepoint
Before intervention and 8 weeks after initiation of Spirulina supplementation
Method of measurement
SCCAI questionnaire

Secondary outcomes

1

Description
Weight
Timepoint
Before intervention and 8 weeks after initiation of spirulina supplementation
Method of measurement
Use scales

2

Description
Body mass index
Timepoint
Before intervention and 8 weeks after initiation of spirulina supplementation
Method of measurement
Calculation

3

Description
Waist
Timepoint

Before intervention and 8 weeks after initiation of spirulina supplementation
Method of measurement
measurement

4

Description
Neck circumference
Timepoint
Before intervention and 8 weeks after initiation of spirulina supplementation
Method of measurement
Measurement

5

Description
Hip circumference
Timepoint
Before intervention and 8 weeks after initiation of spirulina supplementation
Method of measurement
Measurement

6

Description
Blood pressure
Timepoint
Before intervention and 8 weeks after initiation of spirulina supplementation
Method of measurement
Measurement

7

Description
Dietary intake
Timepoint
Before intervention and 8 weeks after initiation of spirulina supplementation
Method of measurement
24-h recall

8

Description
Fatigue
Timepoint
Before intervention and 8 weeks after initiation of spirulina supplementation
Method of measurement
FSS questionnaire

9

Description
Physical activity
Timepoint
Before intervention and 8 weeks after initiation of spirulina supplementation
Method of measurement

IPAQ questionnaire

10

Description

Quality of life

Timepoint

Before intervention and 8 weeks after initiation of spirulina supplementation

Method of measurement

SIBDQ-9 questionnaire

11

Description

Sleep Quality

Timepoint

Before intervention and 8 weeks after initiation of spirulina supplementation

Method of measurement

Pittsburgh Sleep Quality Questionnaire

12

Description

Sleep duration

Timepoint

Before intervention and 8 weeks after initiation of spirulina supplementation

Method of measurement

Pittsburgh Sleep Quality Questionnaire

13

Description

Subjective sleep quality

Timepoint

Before intervention and 8 weeks after initiation of spirulina supplementation

Method of measurement

Pittsburgh Sleep Quality Questionnaire

14

Description

Sleep latency

Timepoint

Before intervention and 8 weeks after initiation of spirulina supplementation

Method of measurement

Pittsburgh Sleep Quality Questionnaire

15

Description

Sleep efficiency

Timepoint

Before intervention and 8 weeks after initiation of spirulina supplementation

Method of measurement

Pittsburgh Sleep Quality Questionnaire

16

Description

Sleep disturbances

Timepoint

Before intervention and 8 weeks after initiation of spirulina supplementation

Method of measurement

Pittsburgh Sleep Quality Questionnaire

17

Description

Use of sleep medication

Timepoint

Before intervention and 8 weeks after initiation of spirulina supplementation

Method of measurement

Pittsburgh Sleep Quality Questionnaire

18

Description

Day-time dysfunction

Timepoint

Before intervention and 8 weeks after initiation of spirulina supplementation

Method of measurement

Pittsburgh Sleep Quality Questionnaire

19

Description

Depression status

Timepoint

Before intervention and 8 weeks after initiation of spirulina supplementation

Method of measurement

DASS 21 questionnaire

20

Description

Stress status

Timepoint

Before intervention and 8 weeks after initiation of spirulina supplementation

Method of measurement

DASS 21 questionnaire

21

Description

Anxiety status

Timepoint

Before intervention and 8 weeks after initiation of spirulina supplementation

Method of measurement

DASS 21 questionnaire

22

Description

Stool frequency

Timepoint

Before intervention and 8 weeks after initiation of spirulina supplementation

Method of measurement

SIBDQ-9 questionnaire

23

Description

Bowel distress and cramp

Timepoint

Before intervention and 8 weeks after initiation of spirulina supplementation

Method of measurement

SIBDQ-9 questionnaire

24

Description

Gas excretion of bowel

Timepoint

Before intervention and 8 weeks after initiation of spirulina supplementation

Method of measurement

SIBDQ-9 questionnaire

25

Description

Flatulence

Timepoint

Before intervention and 8 weeks after initiation of spirulina supplementation

Method of measurement

SIBDQ-9 questionnaire

Intervention groups

1

Description

Intervention group: People entering the study will have mild or moderate level of ulcerative colitis, ranging in age from 18 to 65 years old (n=40). The group of patients will receive Spirulina (*Arthrospira platensis*) 1 g daily (receive two 500 mg capsules daily) for 8 weeks.

Category

Treatment - Other

2

Description

Control group: People entering the study will have mild or moderate level of ulcerative colitis, ranging in age from 18 to 65 years old (n=40). The group of patients will receive starch 1 g daily (receive two 500 mg capsules daily) for 8 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Mehdi Zubiri's office

Full name of responsible person

Mohammad hassan entezari

Street address

Hezar jarib

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Email

Smoradi@razi.tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mohammad hassan entezari

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Phone

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Isfahan university of medical science

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

entezari@hlth.mui.ac.ir

Contact

Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Mohammad hassan entezari
Position
Associate professor
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be 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