

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

The effects of *Spirulina Platensis* on anemia status in patients with ulcerative colitis

Protocol summary

Study aim

The aim of the study is evaluating the effects of spirulina supplementation on anemia status in patients with ulcerative colitis

Design

Parallel double-blind (both patients and researchers) randomized controlled clinical trial. The third person places the placebo and spirulina into identical and similar capsules and containers and encodes them randomly. A simple randomization method using random number table is used, and each client receives its own number. In this study 80 individuals will participate. The first group of patients will receive Spirulina 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. Anemia tests are taken from patients before the intervention and at the end of 8 weeks. finally, the result will be studied using SPSS software.

Settings and conduct

This study will be 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

People with mild or moderate level of ulcerative colitis, ranging in age from 18 to 65 years old will be assigned to receive spirulina supplements (n=40) and placebo (n=40). The group of patients in intervention group will receive Spirulina (*Arthrospira platensis*) 1 g daily (receive two 500 mg capsules daily) for 8 weeks, and the group of patients in the control group will receive starch 1 g daily (receive two 500 mg capsules daily) for 8 weeks.

Main outcome variables

anemia status

General information

Reason for update

In the exclusion criteria section, the use of anemia drugs has been added.

Acronym

IRCT registration information

IRCT registration number: **IRCT20170802035460N3**

Registration date: **2020-05-14, 1399/02/25**

Registration timing: **registered_while_recruiting**

Last update: **2021-04-01, 1400/01/12**

Update count: **1**

Registration date

2020-05-14, 1399/02/25

Registrant information

Name

Fateme Parvizi

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 3429 9220

Email address

fatemeparvizi4@gmail.com

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
The effects of Spirulina Platensis on anemia status in patients with ulcerative colitis

Public title
Spirulina Platensis in patients with ulcerative colitis

Purpose
Treatment

Inclusion/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 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. Taking anemia medications

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

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

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

Ethics committee of Kermanshah University of Medical Sciences

Street address

Kermanshah University of Medical Sciences, Daneshgah Ave., Shahid Shiroodi Blvd.

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2020-04-08, 1399/01/20

Ethics committee reference number

KUMS.REC.1398.1141

Health conditions studied

1

Description of health condition studied

Ulcerative colitis

ICD-10 code

K51.9

ICD-10 code description

Ulcerative colitis, unspecified

Primary outcomes

1

Description

Red Blood Cell Count

Timepoint

Before intervention and 8 weeks after initiation of Spirulina supplementation

Method of measurement

Hematology Analysis

2

Description

White blood cell

Timepoint

Before intervention and 8 weeks after initiation of Spirulina supplementation
Method of measurement
Hematology Analysis

3

Description
Hemoglobin
Timepoint
Before intervention and 8 weeks after initiation of Spirulina supplementation
Method of measurement
Hematology Analysis

4

Description
Mean corpuscular volume
Timepoint
Before intervention and 8 weeks after initiation of Spirulina supplementation
Method of measurement
Hematology Analysis

5

Description
Mean corpuscular hemoglobin
Timepoint
Before intervention and 8 weeks after initiation of Spirulina supplementation
Method of measurement
Hematology Analysis

6

Description
Mean corpuscular hemoglobin concentration
Timepoint
Before intervention and 8 weeks after initiation of Spirulina supplementation
Method of measurement
Hematology Analysis

7

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

8

Description
Serum Iron
Timepoint
Before intervention and 8 weeks after initiation of Spirulina supplementation
Method of measurement

Diagnostic kit

9

Description
Hematocrit
Timepoint
Before intervention and 8 weeks after initiation of Spirulina supplementation
Method of measurement
Hematology Analysis

Secondary outcomes

1

Description
Fecal occult blood
Timepoint
Before intervention and 8 weeks after initiation of Spirulina supplementation
Method of measurement
Diagnostic kit

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
Mehdi Zobeiri
Street address
Ejlalieh building
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
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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

Kermanshah 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
Kermanshah University of Medical Sciences
Full name of responsible person
Fateme Parvizi
Position
Investigator of Kermanshah University of Medical Sciences
Latest degree
Master
Other areas of specialty/work

Others
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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