Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Nov 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
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Iran (Islamic Republic of)
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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.

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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

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Sponsors / Funding sources

1

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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
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
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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