

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

The effect of *Portulaca Oleracea* supplement on inflammatory markers, antioxidant status and quality of life in patients with ulcerative colitis

Protocol summary

Study aim

Determining the effect of *portulaca oleracea* supplement on inflammatory markers, antioxidant status and quality of life in patients with ulcerative colitis

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2-3 per 100 patients. Excel software rand function was used for randomization.

Settings and conduct

Patients with mild to moderate ulcerative colitis referred to Rasool Akram Hospital are randomly divided into two groups of supplement and placebo. At the beginning and end of the study, 10 cc of venous blood sample will be taken from each patient. The supplement group will receive 2 capsules of 500 mg of *portulaca oleracea* twice daily after breakfast and dinner for 8 weeks. It is a double-blind study, which means that the researcher and the patient are not aware of the type of pill they are taking (suppository or placebo supplement).

Participants/Inclusion and exclusion criteria

Inclusion criteria: The patient has declared himself to participate in the study. Age 18 years and older
Diagnosis of ulcerative colitis by specialists in the diagnosis and diagnosis of mild to moderate disease
Taking glucocorticosteroids BMI higher than 18.5 and less than 30 No pregnancy and lactation Lack of disease and disease disorders are known autoimmune diseases, cancer, other diseases and infections. Exclusion qualities: Imbalance to continue cooperation No supplementation (patient acceptance and adaptation level is less than 80%). Recurrence of the disease in a way that leads to hospitalization of the patient Treatment of an acute illness (viral diseases, burns, heart attack, etc.)

Intervention groups

Patients with mild to moderate ulcerative colitis

Main outcome variables

Inflammatory markers (ESR, hs-CRP), antioxidant status (SOD, TAC) and quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120415009472N26**

Registration date: **2022-06-29, 1401/04/08**

Registration timing: **prospective**

Last update: **2022-06-29, 1401/04/08**

Update count: **0**

Registration date

2022-06-29, 1401/04/08

Registrant information

Name

Naheed Aryaeian

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

aryaeian.n@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-21, 1401/04/30

Expected recruitment end date

2023-03-21, 1402/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Portulaca Oleracea supplement on inflammatory markers, antioxidant status and quality of life in patients with ulcerative colitis

Public title

The effect of Portulaca Oleracea on ulcerative colitis

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

The patient has expressed his / her consent to participate in the study. Age 18 years and older
Diagnosis of ulcerative colitis by a gastroenterologist and determination of the severity of the disease in mild to moderate stage
Taking glucocorticosteroids BMI higher than 18.5 and less than 30
No pregnancy and lactation
Do not take supplements (antioxidants, omega 3, etc.) in the last quarter (except for routine supplements prescribed for ulcerative colitis)
No decision to become pregnant during the intervention
Lack of other diseases and obvious intestinal disorders, known autoimmune diseases, cancer, inflammatory and infectious diseases
No edema due to heart and kidney disease

Exclusion criteria:

Reluctance to continue cooperation
No supplementation (patient acceptance and adaptation level is less than 80%).
Recurrence of the disease in a way that leads to hospitalization of the patient
Migration
Changing the type and dose of the patient's drugs during the intervention
Sudden onset of an acute illness (bacterial and viral infections, burns, heart attack, etc.)
Taking anticoagulants such as warfarin or heparin
Taking antihistamines and NSAIDs (ibuprofen, aspirin, diclofenac)
Taking contraceptives
During menstruation
women

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

According to the sample size of 100 that has been determined, the randomization list is generated by a statistician in the form of random blocks in volume 4, taking into account 2 groups A and B (portulaca and placebo). Then, the Faculty of Pharmacy of the University of Tehran will do the packing according to the randomization list during the packing and will be assigned to the patients according to it. After performing

the experiments and completing the study, a random list will be given to the researcher and the analysis will be performed. Until the end of the data analysis, the researcher, patient and analyst will not be informed of the type of drug and placebo and this issue will remain confidential. In case of deviation from the protocol, the analysis method will be used for treatment.

Blinding (investigator's opinion)

Double blinded

Blinding description

Given that this study is a double-blind study, it means that the researcher, patient and analyst are not aware of the type of pill used (portulaca oleracea supplement or placebo). To do this, the relevant capsules are packed in similar packages with the same information and instructions and are coded as A and B by someone other than the interferer so that the interferer is not informed of the type of capsule received by each. The group is viewed.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Tehran Hemmat Highway next to Milad Tower

City

Tehran

Province

Tehran

Postal code

۱۴۳۹۶۱۴۵۳۵

Approval date

2022-05-09, 1401/02/19

Ethics committee reference number

IR.IUMS.REC.1401.110

Health conditions studied

1

Description of health condition studied

Patients with ulcerative colitis

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

High-Sensitivity C-Reactive Protein (hs-CRP)

Timepoint

Measurements at the beginning of the study (before the intervention) and 8 weeks after taking portulaca oleracea supplement

Method of measurement

It is calculated by calorimetric method and by autoanalyzer. enzyme-linked immunosorbent assay(ELISA)

2

Description

Total antioxidant capacity (TAC)

Timepoint

Measurements at the beginning of the study (before the intervention) and 8 weeks after taking portulaca oleracea supplement

Method of measurement

chromatography

3

Description

Erythrocyte sedimentation rate(ESR)

Timepoint

Measurements at the beginning of the study (before the intervention) and 8 weeks after taking portulaca oleracea supplement

Method of measurement

Vacuum tube erythrocyte sedimentation rate

4

Description

Superoxide dismutase(SOD)

Timepoint

Measurements at the beginning of the study (before the intervention) and 8 weeks after taking portulaca oleracea supplement

Method of measurement

Spectrophotometry

5

Description

Quality of Life

Timepoint

Measurements at the beginning of the study (before the intervention) and 8 weeks after taking portulaca oleracea supplement

Method of measurement

Questionnaire (IBDQ9)

Secondary outcomes

1

Description

Body Mass Index(BMI)

Timepoint

At the beginning of the study (before the intervention) and 8 weeks after starting portulaca oleracea supplement

Method of measurement

Weight in kg per square meter in height in meters

2

Description

waist circumference

Timepoint

At the beginning of the study (before the intervention) and 8 weeks after starting portulaca oleracea supplement

Method of measurement

The shortest distance around the waist, below the chest and above the navel

3

Description

Intensity of physical activity

Timepoint

At the beginning of the study (before the intervention) and 8 weeks after starting portulaca oleracea supplement

Method of measurement

The amount of physical activity of individuals during the last 7 days in terms of metabolic equivalent

Intervention groups

1

Description

Intervention group: For 8 weeks, they will receive two capsules of 500 mg of portulaca oleracea a day, with food, twice after breakfast and dinner, which are prepared by "Perpin Elixir Global" company.

Category

Treatment - Drugs

2

Description

Control group: For 8 weeks, they will receive two 500 mg maltodextrin capsule capsules a day, with food, twice after breakfast and dinner, which are prepared by Perpin Elixir Global.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasool Akram Hospital

Full name of responsible person

Professor Shahram Agah

Street address

Tehran-Sattar Khan-Niayesh St.-Corner of Mansouri
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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

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Full name of responsible person

Mrs.Bolandian

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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

Iran 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**

Iran University of Medical Sciences

Full name of responsible person

Dr. Nahid Aryaeian

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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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

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Title and more details about the data/document

Unidentifiable personal data of participants; Only part of the data such as the original outcome information

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

Researchers working in academic and scientific institutions

From where data/document is obtainable

n-aryaeian@sina.tums.ac.ir

rahimy.reihaneh97@gmail.com

What processes are involved for a request to access data/document

Document request email, applicant review, after confirmation, documents will be provided to the applicant.

Comments