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

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Naheed Aryaeian

Name of organization / entity
Iran 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
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
۱۴۴۹۶۱۴۵۳۵

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

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Tehran-Sattar Khan-Niayesh St.-Corner of Mansouri St.-Hazrat Rasoul Akram Hospital (PBUH)
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Sponsors / Funding sources

1

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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
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
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Full name of responsible person
Dr. Nahid Aryaeian
Position
Associate Professor
Latest degree
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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