

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

The effect of grape seed extract on the expression of genes mediating immunity, inflammation, disease severity and quality of life in patients with ulcerative colitis

Protocol summary

Study aim

Determining the effect of grape seed extract on the expression of genes mediating immunity, inflammation, disease severity, and quality of life in patients with ulcerative colitis.

Design

A controlled, parallel-group, triple-blind, randomized, phase 3 clinical trial on 66 patients with ulcerative colitis

Settings and conduct

Ulcerative colitis patients referred to Rasoul Akram Hospital, who meet the inclusion criteria, are randomly divided into two groups: the intervention group (receiving grape seed extract) and the placebo control group for 12 weeks

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 18 to 65 years, BMI between 18.5 and 35 kg/m², Diagnosis of ulcerative colitis in the mild to moderate stage by a gastroenterologist, Patients using one of the drug groups, such as 5-aminosalicylic acid (Petasa, Mesalazine, or Asacol). Exclusion criteria: Pregnancy and breastfeeding, Taking anticoagulants such as warfarin or heparin, Suffering from other intestinal diseases, autoimmune diseases, cancer, inflammatory diseases, and infectious diseases.

Intervention groups

Intervention group: Grape seed extract (600 mg/day), prepared by Barij Essan Pharmaceutical Company.
Placebo group: placebo (600 mg/day) prepared by Barij Essan Pharmaceutical Company.

Main outcome variables

Expression of genes such as T-bet, GATA3, ROR- γ t, FOXP3, Serum concentrations of IL-17, hs-CRP, MDA, SOD, TAC, GPX, Measurement of ESR, IBDQ-9 and SCCAI-Q questionnaires

General information

Reason for update

Variables (MDA, SOD, TAC, GPX), with the aim of conducting a secondary study entitled "The Effect of Grape Seed Extract on Antioxidant Status in Patients with Ulcerative Colitis," approved with the ethics code R.IUMS.REC.1403.895, were added to the present study. This study will be conducted after the end of the main study on the patients' serum. The sample size of the main study was changed to 66 people due to lack of funding based on citation of evidence (article).

Acronym

IRCT registration information

IRCT registration number: **IRCT20120415009472N28**
Registration date: **2023-09-05, 1402/06/14**
Registration timing: **prospective**

Last update: **2025-05-26, 1404/03/05**

Update count: **1**

Registration date

2023-09-05, 1402/06/14

Registrant information

Name

Naheed Aryaeian

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-07, 1402/07/15

Expected recruitment end date

2024-10-06, 1403/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of grape seed extract on the expression of genes mediating immunity, inflammation, disease severity and quality of life in patients with ulcerative colitis

Public title

The effect of grape seed extract in ulcerative colitis

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

BMI of patients between 18.5-35 kg/m² Diagnosis of ulcerative colitis in the mild to moderate stage by a gastroenterologist based on patient tests, patient symptoms (disease severity questionnaire) and colonoscopy. Patients using one of the drug groups (5-aminosalicylic acid (Petasa, Mesalazine or Asacol).

Exclusion criteria:

Pregnancy and breastfeeding Taking anticoagulants such as warfarin or heparin Suffering from other intestinal diseases, autoimmune diseases, cancer, inflammatory diseases, and infectious diseases.

Age

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

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

A person outside the study is asked to randomly assign the letter A or B to the cans of supplement and placebo by flipping a coin, and then hand the cans to the researcher. It is used to randomize patients to receive packages A and B using random number generation software. After analyzing the data, the person outside the study will be requested to provide the names of the drug and placebo labels to be utilized in the results and discussion section.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Supplement and placebo will be categorized based on random codes. The researcher, gastroenterologist, individuals involved in sample evaluation, and the person conducting statistical analysis will be blinded to the intervention or control group assignment.

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

Research and Technology Vice-Chancellor, Central Headquarters Building, Iran University of Medical Sciences, next to Milad Tower, Hammet Highway, Tehran

City

Tehran

Province

Tehran

Postal code

14496-14535

Approval date

2023-08-09, 1402/05/18

Ethics committee reference number

IR.IUMS.REC.1402.451

Health conditions studied**1****Description of health condition studied**

Patients with ulcerative colitis

ICD-10 code

K51

ICD-10 code description

Ulcerative colitis

Primary outcomes**1****Description**

T-bet gene expression

Timepoint

At the beginning of the study and the twelfth week

Method of measurement

Real-time PCR

2

Description

GATA3 gene expression

Timepoint

At the beginning of the study and the twelfth week

Method of measurement

Real-time PCR

3

Description

ROR- γ gene expression

Timepoint

At the beginning of the study and the twelfth week

Method of measurement

Real-time PCR

4

Description

FOXP3 gene expression

Timepoint

At the beginning of the study and the twelfth week

Method of measurement

Real-time PCR

5

Description

Serum concentration of hs-CRP

Timepoint

At the beginning of the study and the twelfth week

Method of measurement

Eliza

6

Description

Serum concentration of IL-17

Timepoint

At the beginning of the study and the twelfth week

Method of measurement

Eliza

7

Description

ESR

Timepoint

At the beginning of the study and the twelfth week

Method of measurement

westergren

8

Description

Disease Severity(SCCAI-Q)

Timepoint

At the beginning of the study and the twelfth week

Method of measurement

Severity of Disease Questionnaire (SCCAI-Q)

9

Description

Quality of Life(IBDQ-9)

Timepoint

At the beginning of the study and the twelfth week

Method of measurement

Quality of life questionnaire(IBDQ-9)

10

Description

Total Antioxidant Capacity

Timepoint

At the beginning of the study and at the end of week 12

Method of measurement

TAC concentration in serum using an ELISA kit

11

Description

Malondialdehyde (MDA)

Timepoint

At the beginning of the study and at the end of week 12

Method of measurement

MDA concentration in serum using an ELISA kit

12

Description

Superoxide dismutase (SOD)

Timepoint

At the beginning of the study and at the end of week 12

Method of measurement

SOD concentration in serum using an ELISA kit

13

Description

Glutathione peroxidase (GPX)

Timepoint

At the beginning of the study and at the end of week 12

Method of measurement

GPX concentration in serum using an ELISA kit

Secondary outcomes

1

Description

BMI

Timepoint

At the beginning of the study and the twelfth week

Method of measurement

Weight(kg)/ (height)m²

Intervention groups

1

Description

Intervention group: Patients will receive 600 mg/day (two tablets of 300 mg) of grape seed extract, which will be

prepared by Barij Essan Pharmaceutical Company, for a duration of 12 weeks.

Category

Treatment - Drugs

2**Description**

Control group:Patients will receive 600 mg/day (two tablets of 300 mg) of placebo, which will be prepared by Barij Essan Pharmaceutical Company, for a duration of 12 weeks.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Rasoul Akram Hospital, Tehran

Full name of responsible person

Elham Pishgar

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Dr. Reza Falak, Head of Deputy of Research and Technology, Iran University of Medical Sciences

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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

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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Other areas of specialty/work

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Fax**Email**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is 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

The access period starts 6 months after the results are published

To whom data/document is available

Only for researchers working in academic and scientific institutions

Under which criteria data/document could be used

To conduct studies

From where data/document is obtainable

Dr. Nahid Aryaeian : aryaeian.n@iums.ac.ir

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

Request by e-mail along with providing a complete explanation of why the data is needed

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Dr. Nahid Aryaeian

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

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