

# 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/m<sup>2</sup>, 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- $\gamma$ 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

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Iran (Islamic Republic of)

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+98 21 8670 4750

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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/m<sup>2</sup> 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

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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- $\gamma$  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)m<sup>2</sup>

## **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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Niyayesh St., Satarkhan St

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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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rezafalak@yahoo.com

**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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**Position**

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**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**

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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