Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 Oct 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 between18.5 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-γt, FOXp,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)
Phone
+98 21 8670 4750
Email address
aryaeian.n@iums.ac.ir

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-tgene 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^2

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

Street address

Niyayesh St., Satarkhan St

City

Tehran

Province

Tehran

Postal code

1445613131

Phone

+98 21 6435 1000

Email

dr.elhampishgar@gmail.com

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

Street address

Iran University of Medical Sciences, next to Milad Tower, Hammet Highway

City

Tehran

Province

Tehran

Postal code

14496-14535

Phone

+98 21 8862 2703

Email

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

Street address

Tehran, Hemmat Highway next to Milad Tower, Iran University of Medical Sciences, , School of Public Health

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Phone

+98 21 8670 4734

Email

aryaeian.n@iums.ac.ir

Person responsible for scientific 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

Street address

University of Medical Sciences, next to Milad Tower, Hammet Highway, Tehran

City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
Phone
+98 21 8670 4734
Fax
Email
aryaeian.n@iums.ac.ir

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
Nutrition
Street address
School of Public Health,Iran University of Medical Sciences, next to Milad Tower, Hammet Highway, Tehran
City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
Phone
+98 21 8670 4734
Email
aryaeian.n@iums.ac.ir

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