Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Comparison of Extra Virgin Olive Oil and Canola Oil on Clinical Outcomes and Inflammatory Markers (hsCRP, TNF-α) among Patients with Ulcerative Colitis(UC)

Protocol summary

Study aim

Comparison of Extra Virgin Olive Oil and Canola Oil on Clinical Outcomes and Inflammatory Markers (hsCRP, TNF-α) among Patients with Ulcerative Colitis(UC)

Design

The present study is a randomized, cross-over, and single-blind phase 2-3 clinical trial, will be carried out on 30 patients with ulcerative colitis, referred to Imam Khomeini Hospital clinic, and Gastrointestinal Specialist confirmed their disease. Patients are randomly divided into two groups, each group uses Extra Virgin Olive oil or Canola oil, in different order. Group 1: First, Extra Virgin Olive oil, then Canola oil, Group 2: First, Canola oil, then Extra Virgin Olive oil. Assignment of patients to each group of the study will be done by random block method using four blocks (based on the weight variable). Sampling will be done in Simple Random Non-probability Sampling way, so that from the start of the study, all patients who have the inclusion criteria and who do not have exclusion criteria will be selected as samples, and this will continue until to achieve final sample size.

Settings and conduct

The aim of this study is to compare the effect of Extra Virgin Olive oil and Canola oil on inflammatory markers as a complementary treatment in patients with ulcerative colitis at Imam Khomeini Hospital, Ahvaz. This study is Cross-over. Patients are randomly divided into two groups (Extra Virgin Olive Oil/and or Canola oil) and use oils in different order. The type of blindness in this study is single-blind, so that the person who evaluates the outcome of the treatment (data analyst) is not aware of the type of treatment.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Ulcerative colitis, confirmed by histopathology The severity of the disease is mild to moderate Non-infectious, autoimmune and inclusive diseases (including cancer, kidney disease, rheumatoid arthritis, liver, AIDS, and cardiovascular disease) No use of ω3 supplements, fish oil Body mass index ranges from 18.5 to 30 Sex is male The age range is between 18 and 75 years old People's Inclination to collaborate on the plan Exclusion criteria: The patient is in the acute phase of the disease The patient does not tolerate the recommended oils reluctancy to continue cooperation in this research

Intervention groups

Cross-over intervention Group 1: First, Extra Virgin Olive oil, then Canola oil, Group 2: First, Canola oil, then Extra Virgin Olive oil

Main outcome variables

Serum hs-CRP; Serum TNF-α; Serum ESR; Stool frequency per day; Frequency of rectal bleeding per day

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170730035381N1**
Registration date: **2017-12-28, 1396/10/07**
Registration timing: **prospective**

Last update: **2017-12-28, 1396/10/07**
Update count: **0**

Registration date

2017-12-28, 1396/10/07

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3221 6104

Email address

morvaridi.m@ajums.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-01-21, 1396/11/01
Expected recruitment end date
2018-08-23, 1397/06/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of Extra Virgin Olive Oil and Canola Oil on Clinical Outcomes and Inflammatory Markers (hsCRP, TNF-α) among Patients with Ulcerative Colitis(UC)

Public title
Comparison of Extra Virgin Olive Oil and Canola Oil in Treatment of Patients with Ulcerative Colitis(UC)
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Ulcerative colitis, confirmed by histopathology The severity of the disease is mild to moderate Non-infectious, autoimmune and inclusive diseases (including cancer, kidney disease, rheumatoid arthritis, liver, AIDS, and cardiovascular disease) No use of ω3 supplements, fish oil Body mass index ranges from 18.5 to 30 The patient should not be pregnant or breastfeeding The age range is between 18 and 75 years old People's Inclination to collaborate on the plan
Exclusion criteria:
The patient is in the acute phase of the disease The patient does not tolerate the recommended oils reluctancy to continue cooperation in this research
Age
From **18 years** old to **75 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **32**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization in this study will be done by block method, which means that the researcher divides individuals into subgroups called blocks. The randomization unit in this study is a block and the number of people in each block is similar and four. Assignment of patients to each groups of the treatment will be done by using these blocks. In this method, SAS algorithm software is used to make random sequences and determine the type of treatment assigned to each patient. Concealment will also be done by placing the type of treatment assigned to each person in the envelope, so that the person providing the treatment is unaware.
Blinding (investigator's opinion)
Single blinded
Blinding description
The type of blindness in our study will be single-blind, so that the person who evaluate the outcomes of the study (data analyzer), does not know the type of treatment assigned to each patient. The type of treatment and its order is characterized by coding. In this study, due to the nature of complementary treatment (Extra Virgin Olive oil and Canola Oil), there is no possibility for blinding participant, clinician and researcher.
Placebo
Not used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
•Ethics committee of Ahvaz Jundishapur University of Medical Sciences
Street address
Ethics committee in research, Vice Chancellor for Research and Technology, Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd., Ahvaz
City
Ahvaz
Province
Khouzestan
Postal code
61357-15794
Approval date
2017-11-25, 1396/09/04
Ethics committee reference number
IR.AJUMS.REC.1396.624

Health conditions studied

1

Description of health condition studied
Ulcerative colitis
ICD-10 code
K51
ICD-10 code description
Ulcerative colitis

Primary outcomes

1

Description
Serum hs-CRP
Timepoint
The beginning of the study - the end of the twentieth day
Method of measurement
ELISA

2

Description
Serum TNF-α
Timepoint
The beginning of the study - the end of the twentieth day
Method of measurement
ELISA

3

Description
Serum ESR
Timepoint
The beginning of the study - the end of the twentieth day
Method of measurement
ELISA

4

Description
Stool frequency per day
Timepoint
The beginning of the study - the end of the twentieth day
Method of measurement
Mayo score

5

Description
Frequency of rectal bleeding per day
Timepoint
The beginning of the study - the end of the twentieth day
Method of measurement
Mayo score

Secondary outcomes

1

Description
Weight
Timepoint
The beginning of the study - the end of the twentieth day
Method of measurement
Scales

2

Description
Body mass index
Timepoint
The beginning of the study - the end of the twentieth day
Method of measurement
BMI by formula

3

Description
Waist circumference
Timepoint
The beginning of the study - the end of the twentieth day
Method of measurement
Non stretch meter

4

Description
Hip circumference
Timepoint
The beginning of the study - the end of the twentieth day
Method of measurement
Non stretch meter

Intervention groups

1

Description
Extra virgin olive oil; 50 ml once daily; Crossover intervention for 20 days and 14 days wash out; with food in raw form (no frying and cooking oil); Aryan Tame Khazar Co.
Category
Treatment - Other

2

Description
Intervention group: Canola oil; 50 ml once daily; Crossover intervention for 20 days and 14 days wash out; with food in raw form (no frying and cooking oil); Aryan Tame Khazar Co.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Mehrnaz Morvaridi
Street address
Imam Khomeini Hospital, Azadegan Ave., Ahvaz
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology of Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Mohammad Badavi

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Vice Chancellor for Research and Technology, Ahvaz Jundishapur University of Medical Sciences, Golestan Blvd., Ahvaz

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badavi-m@ajums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice Chancellor for Research and Technology of Ahvaz Jundishapur 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

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Mehrnaz Morvaridi

Position

MSc Student

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

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Full name of responsible person

Sima Jafarirad

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Mehrnaz Morvaridi

Position

MSc Student

Latest degree

Bachelor

Other areas of specialty/work
Nutrition
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morvaridi.m@ajums.ac.ir
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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