

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 ω 3 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 reluctance 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 ω 3 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 reluctance to continue cooperation in this research

AgeFrom **18 years** old to **75 years** old**Gender**

Both

Phase

2-3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample sizeTarget 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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Khuzestan

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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

Street address

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

Full name of responsible person

Sima Jafarirad

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Assistant professor

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Other areas of specialty/work

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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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Web page address**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