Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

The effect of zataria multiflora alcoholic extract on clinical symptoms, mediator genes of immunity, inflammatory and oxidative stress indices in patients with ulcerative colitis

Protocol summary

Study aim
Determining the effect of zataria multiflora alcoholic extract on clinical symptoms, mediator genes of immunity, inflammatory and oxidative stress indices in patients with ulcerative colitis

Design
Clinical trial with a control group, with parallel groups, double-blind, randomized, on 96 patients. Block method is used for randomization.

Settings and conduct
The research sample is people suffering from ulcerative colitis referring to Alimentary Tract Research Center of Imam Khomeini Hospital in Ahvaz. The study subjects will be randomly divided into two groups: the intervention group (receive 6 mg per kilogram of body weight per day of zataria multiflora extract for 2 months) and the control group (receive placebo for 2 months)

Participants/Inclusion and exclusion criteria
Inclusion criteria include age 18 to 65 years, BMI 18.5 to 35 kg/m2, diagnosis of ulcerative colitis by a gastroenterologist. The duration of the disease should not be less than 6 months and not more than 5 years. Exclusion criteria are patients with the acute phase of the disease, the presence of autoimmune diseases and other inflammatory diseases, thyroid disease, history of gastrointestinal surgery, diabetes mellitus, pregnancy and lactation, history of allergy to thyme

Intervention groups
Zataria multiflora extract, which is prepared from the Giah Essence company (Gorgan, Iran).To prepare the placebo, 5% alcohol is dissolved in simple syrup (80% by weight by volume of sucrose). Also, the placebo color is changed to yellow with sunset color (FD&C Yellow #6). The intervention group (receiving 6 mg per kilogram of body weight per day of zataria multiflora extract for 2 months) and the control group (receiving placebo for 2 months)

Main outcome variables
Inflammatory indices including hs-CRP, IFN-γ IL-17, oxidative indices including MDA and TAC

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120415009472N27**
Registration date: **2023-08-30, 1402/06/08**
Registration timing: **prospective**

Last update: **2023-08-30, 1402/06/08**
Update count: **0**

Registration date
2023-08-30, 1402/06/08

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
2023-09-06, 1402/06/15

Expected recruitment end date
2024-03-05, 1402/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of zataria multiflora alcoholic extract on clinical symptoms, mediator genes of immunity, inflammatory and oxidative stress indices in patients with ulcerative colitis

Public title

Investigating the effect of zataria multiflora in ulcerative colitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Body mass index 18.5 to 35 kg/m2 Diagnosing ulcerative colitis by a gastroenterologist based on the Rome III Diagnostic Criteria for functional digestive disorders (flatulence, constipation and diarrhea), the Mayo score system, colonoscopy and laboratory findings Disease duration more than 6 months and less than 5 years

Exclusion criteria:

Patients with the acute phase of the disease Suffering from autoimmune diseases and other inflammatory diseases (renal, cardiovascular, liver diseases, types of cancer and acquired immunodeficiency syndrome (HIV)) Thyroid disorders History of gastrointestinal surgeries Diabetes Mellitus Pregnancy and lactation History of allergy to zataria multiflora

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **92**

Randomization (investigator's opinion)

Randomized

Randomization description

The participants will be divided into two groups by block randomization method: intervention group and control group. The randomization list is produced by a statistician in the form of random blocks with a volume of 4 and considering 2 groups A and B (zataria multiflora and placebo). Then, during packing, randomization of the packages will be done according to the list and allocated to the patients accordingly. After conducting experiments and completing the study, a random list will be given to the researcher and analysis will be done. Until the end of the data analysis, the patient and the analyst will not be informed about the type of drug and placebo, and this issue will remain confidential. In case of deviation from the protocol, the analysis method will be used with the intention of treatment.

Blinding (investigator's opinion)

Double blinded

Blinding description

Considering that this study is double-blind in the sense that the researcher, the patient and the analyst do not know what type of dietary supplement is being taken (Zataria Multiflora supplement or placebo). To accomplish this task, the extract and placebo are packaged in similar bottles with the same information and instructions, and coded as A and B by someone other than the interventionist, so the interventionist is unaware of the capsule type. The values obtained from each group should be noted.

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

۱۴۴۹۶۱۴۵۳۵

Approval date

2023-06-13, 1402/03/23

Ethics committee reference number

IR.IUMS.REC.1402.207

Health conditions studied

1

Description of health condition studied

Patients with ulcerative colitis

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

High-Sensitivity C-Reactive Protein (hs-CRP)

Timepoint

Measurements at the beginning of the study (before the intervention) and 2 months after taking zataria multiflora supplement

Method of measurement

It is measured by colorimetric method and by autoanalyzer. enzyme-linked immunosorbent assay(ELISA)

2

Description

Erythrocyte sedimentation rate(ESR)

Timepoint

Measurements at the beginning of the study (before the intervention) and 2 months after taking zataria multiflora supplement

Method of measurement

Vacuum tube erythrocyte sedimentation rate

3

Description

Interferon gamma (IFN-γ)

Timepoint

Measurements at the beginning of the study (before the intervention) and 2 months after taking zataria multiflora supplement

Method of measurement

It is measured by colorimetric method and by autoanalyzer. enzyme-linked immunosorbent assay(ELISA)

4

Description

Interleukin 17 (IL17)

Timepoint

Measurements at the beginning of the study (before the intervention) and 2 months after taking zataria multiflora supplement

Method of measurement

It is measured by colorimetric method and by autoanalyzer. enzyme-linked immunosorbent assay(ELISA)

5

Description

Total antioxidant capacity (TAC)

Timepoint

Measurements at the beginning of the study (before the intervention) and 2 months after taking zataria multiflora supplement

Method of measurement

Chromatography

6

Description

Malondialdehyde (MDA)

Timepoint

Measurements at the beginning of the study (before the intervention) and 2 months after taking zataria multiflora supplement

Method of measurement

Spectrophotometry

7

Description

nuclear factor kappa light chain enhancer of activated B cells (NF-κB)

Timepoint

Measurements at the beginning of the study (before the intervention) and 2 months after taking zataria multiflora supplement

Method of measurement

Real time PCR

8

Description

T-box transcription factor (T-bet)

Timepoint

Measurements at the beginning of the study (before the intervention) and 2 months after taking zataria multiflora supplement

Method of measurement

Real time PCR

9

Description

GATA Binding Protein 3 (GATA3)

Timepoint

Measurements at the beginning of the study (before the intervention) and 2 months after taking zataria multiflora supplement

Method of measurement

Real time PCR

10

Description

Forkhead box P3 (FOXP3)

Timepoint

Measurements at the beginning of the study (before the intervention) and 2 months after taking zataria multiflora supplement

Method of measurement

Real time PCR

11

Description

RAR-related orphan receptor gamma (RORγt)

Timepoint

Measurements at the beginning of the study (before the intervention) and 2 months after taking zataria multiflora supplement

Method of measurement

Real time PCR

Secondary outcomes

1

Description
Body Mass Index(BMI)
Timepoint
Measurements at the beginning of the study (before the intervention) and 2 months after taking zataria multiflora supplement
Method of measurement
Weight in kg per square meter in height in meters

2

Description
Waist circumference
Timepoint
Measurements at the beginning of the study (before the intervention) and 2 months after taking zataria multiflora supplement
Method of measurement
The shortest distance around the waist, below the chest and above the navel

3

Description
Intensity of physical activity
Timepoint
Measurements at the beginning of the study (before the intervention) and 2 months after taking zataria multiflora supplement
Method of measurement
The amount of physical activity of individuals during the last 7 days in terms of metabolic equivalent

Intervention groups

1

Description
Intervention group: Patients will receive 6 mg per kilogram of body weight per day of zataria multiflora extract for a period of 2 months along with food in three times after breakfast, lunch and dinner, which are provided by "Giah Essence Phitopharm Co.".
Category
Treatment - Drugs

2

Description
Control group: Patients will receive 6 mg per kilogram of body weight per day of placebo for 2 months with food in three times after breakfast, lunch and dinner, which is prepared in the pharmacology laboratory of Ahvaz University of Medical Sciences.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Alimentary Tract Research Center, Imam Khomeini Hospital Clinical Research Development Unit, Ahvaz
Full name of responsible person
Dr. Seyed Saeed Seyedian
Street address
Alimentary Tract Research Center, 4th floor, Imam Khomeini Hospital, Azadegan Ave., Ahvaz
City
Ahvaz
Province
Khouzestan
Postal code
6193673111
Phone
+98 61 3221 6504
Email
RDS@ajums.ac.ir

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, Tehran
City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
Phone
+98 21 8862 2703
Email
Falak.r@iums.ac.ir
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
Faculty of 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
n-aryaeian@sina.tums.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
Faculty of 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
n-aryaeian@sina.tums.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
Faculty of 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
n-aryaeian@sina.tums.ac.ir
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
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
Access period starts 6 months after the results are published
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
Researchers working in academic and scientific institutions
From where data/document is obtainable
n-aryaeian@sina.tums.ac.ir, morvaridi.m@iums.ac.ir

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

Document request email, applicant review, after confirmation, documents will be provided to the applicant.

Comments