

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Effect of rose oil soft gel on controlling the symptoms of ulcerative colitis in comparison to placebo: a randomized double blind placebo controlled trial

Protocol summary

Summary

Purpose : In this study, we compare rose oil soft gel with placebo in controlling the clinical symptoms of ulcerative colitis. Design of study and performance: This study is a randomized double blind placebo controlled trial in one center (Motahari Clinic) that perform On patients with ulcerative colitis that previously confirmed with colonoscopy , age> 18-70 years and at present have mild to moderate disease based on mayo clinic score. The main exclusion criteria are history of steroid use in the past 4 weeks, any NSAIDs in one week before, and the history of antibiotic use and any medicinal plants within 2 weeks before entering the study. 80 Samples select from target population that randomly assign at least 40 patients to each of two treatment arms. Patients randomly assign to receive either placebo(Sesame Oil soft gel) or rose oil soft gel, two capsule three times daily for two months with routine medications. Patients will be followed for 2 months. Patients will be visited 3 times, one at arrival and 2 times at the end of each month. Clinical symptoms and quality of life the patients will be evaluate with mayoclinic-6 standard form and IBDQ-9(Farsi version). The mayo clinic-6 standard form will be filled in at first visit and then weekly during 2 months of treatment by the patient, and IBDQ-9 will be filled in at the beginning of the study and after 2 months of treatment by the therapist. The CRP will be tested at beginning and end of the study. The primary outcome is control of clinical symptoms. possible side effects of medications will also record in the drug side effect registration questionnaire.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016120323823N2**

Registration date: **2017-07-21, 1396/04/30**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-07-21, 1396/04/30

Registrant information

Name

Ali Tavakoli

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3233 1028

Email address

tavakkolia@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

barijessence company and Shiraz University Of Medical Sciences

Expected recruitment start date

2017-07-23, 1396/05/01

Expected recruitment end date

2018-03-19, 1396/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of rose oil soft gel on controlling the symptoms of ulcerative colitis in comparison to placebo: a randomized

double blind placebo controlled trial

Public title
Effect of rose oil soft gel on controlling the symptoms of ulcerative colitis

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: patients with ulcerative colitis that previously confirmed with colonoscopy ;age> 18-70 years. exclusion criteria: history of steroid use in the past 4 weeks; history of any NSAIDs use in one week before; history of antibiotic use within 2 weeks before entering the study; any medicinal plants within 2 weeks before entering the study.

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shiraz University Of Medical Sciences

Street address
Zand Strret

City
Shiraz

Postal code

Approval date
2016-03-06, 1394/12/16

Ethics committee reference number
IR.SUMS.REC.1394.211

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
clinical symptoms

Timepoint
in at first visit and then weekly during 2 months of treatment

Method of measurement
mayo clinic-6 standard form

2

Description
quality of life

Timepoint
in at the beginning of the study and after 2 months of treatment

Method of measurement
IBDQ-9(Farsi version)

3

Description
CRP test

Timepoint
Before the intervention and end of the intervention(2 months)

Method of measurement
Device

4

Description
fecal calprotectin

Timepoint
Before the intervention and end of the intervention(2 months)

Method of measurement
stool exam

Secondary outcomes

1

Description
side effect

Timepoint
daily

Method of measurement
drug side effect registration questionnaire

Intervention groups

1

Description

80 Samples select from target population that assign at least 40 patients to each of two treatment arms. Patients in interventional group receive rose oil soft gel, two capsule three times. oral, daily, for two months.

Category

Treatment - Drugs

2

Description

Patients in control group receive placebo(Sesame Oil soft gel) two capsule three times,oral. daily for two months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Motahari Clinic

Full name of responsible person

dr. Ali Tavakoli

Street address

Namazi Square,Zand Street

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University Of Medical Sciences and barijessence company

Full name of responsible person

dr. Basir Hashemi

Street address

Zand Street

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz University Of Medical Sciences and barijessence company

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz University Of Mdical Sciences

Full name of responsible person

dr.Ali Tavakoli

Position

MD/phd student of traditional medicin

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University Of Medical Sciences

Full name of responsible person

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Position

Research Center for Traditional Medicine and History of Medicine/phd of traditional medicine

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

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Position

MD/phd student of traditional medicien

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty