Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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
Street address
Zand Street
City
Shiraz
Postal code
Phone
+98 71 3233 1028
Fax
Email
tavakkolia@sums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz University Of Medical Sciences
Full name of responsible person
dr.Mehdi Pasalar
Position
Research Center for Traditional Medicine and History of Medicine/phd of traditional medicine
Other areas of specialty/work
Street address
Zand Street
City
Shiraz
Postal code
Phone
+98 71 3233 7589
Fax
Email
pasalar@sums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Shiraz University Of Medical Sciences
Full name of responsible person
dr. Ali Tavakoli
Position
MD/phd student of traditional medicien
Other areas of specialty/work

Street address
zand street
City
Shiraz
Postal code
Phone
+98 71 3233 1028
Fax
Email
tavakkolia@sums.ac.ir
Web page address

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