

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Effect of Ethanolic extract of Trachyspermum ammi as adjuvant in the reduction of bleeding in patients with IBD

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

Evaluation of the Effect of Ethanolic extract of Trachyspermum ammi as adjuvant in the reduction of bleeding in patients with IBD

Last update: **2021-03-05, 1399/12/15**

Update count: **0**

Registration date

2021-03-05, 1399/12/15

Design

This clinical trial will be performed on 64 patients, divided into two groups of 32, including a control group and parallel groups. A simple double-blind, randomized study will be performed in this study.

Registrant information

Name

Pezhman Sharifi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Settings and conduct

The study is performed in the Liver and Digestive Clinic of Tohid Hospital in Sanandaj. The intervention group is given two 250 mg capsule of Ethanolic extract of Trachyspermum ammi daily for three months, along with standard treatment. The control group is given two placebo daily for three months with standard treatment.

Recruitment status

Recruitment complete

Funding source

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Age 18 to 75 years, Patients diagnosed with ulcerative colitis by a gastroenterologist
Exclusion Criteria: Crohn's disease, Pregnancy, Breastfeeding, History of allergy to herbal medicines

Expected recruitment start date

2021-02-19, 1399/12/01

Expected recruitment end date

2021-10-23, 1400/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Intervention groups

Intervention group: ethanolic extract of Trachyspermum ammi, oral capsule, 250 mg, twice a day for three months with standard treatment. Control group: placebo containing starch, oral capsule, 250 mg, twice a day for three months with standard treatment.

Main outcome variables

number of bowel movements per day; the amount of daily bleeding from the rectum; classification of bleeding by a physician; OB; Hb; CRP; ESR

Scientific title

Effect of Ethanolic extract of Trachyspermum ammi as adjuvant in the reduction of bleeding in patients with IBD

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190415043279N10**

Registration date: **2021-03-05, 1399/12/15**

Public title

Effect of Trachyspermum ammi in the reduction of bleeding in patients with IBD

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age 18 to 75 years Patients diagnosed with Ulcerative colitis by a gastroenterologist

Exclusion criteria:
Crohn's disease Pregnancy Breastfeeding History of allergy to herbal medicines

Age
From **18 years** old to **75 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **64**

Randomization (investigator's opinion)
Randomized

Randomization description
For apply randomization, the permuted block randomization will be used with quadruple blocks. Blocks will be produced by using the online site (www.sealedenvelope.com). Using block randomization method and online statistical software (www.sealedenvelope.com), 64 patients will be divided into two equal groups of intervention and control in 8 blocks of 4. To hide random sequences, the sealed envelope method is used. First, a random sequence is created by one of the mentioned methods. then based on the sample size a number of envelopes with aluminum wrappers (in order to obscure the contents of the envelopes) are prepared and each of the random sequences created is recorded on a card. Finally, the lids of the envelopes are glued and placed inside a box, respectively. At the beginning of the registration of participants, according to the order of entry of eligible participants into the study, one of the envelopes is opened in order and the assigned group of the participant is revealed.

Blinding (investigator's opinion)
Double blinded

Blinding description
All supplements and placebo capsules will be identical with respect to appearance and will differ only in the encoding of the capsules. The treatment code of the intervention supplements will be blind for subjects, investigators and staff involved in the conduct of the study.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kurdistan University of Medical Sciences

Street address

Pasdaran Blvd., Kurdistan University of Medical Sciences

City

Sanandaj

Province

Kurdistan

Postal code

66117713446

Approval date

2020-09-08, 1399/06/18

Ethics committee reference number

IR.MUK.REC.1399.140

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

Number of daily bowel movements

Timepoint

Beginning and end of the intervention

Method of measurement

Disease Activity Questionnaire

2

Description

Daily rectal bleeding

Timepoint

Beginning and end of the intervention

Method of measurement

Disease Activity Questionnaire

3

Description

Classification of bleeding according to symptoms and tests by a physician

Timepoint

Beginning and end of the intervention

Method of measurement

Disease Activity Questionnaire

4**Description**

Fecal occult blood

Timepoint

Beginning and end of the intervention

Method of measurement

Stool test

5**Description**

Blood Hemoglobin

Timepoint

Beginning and end of the intervention

Method of measurement

CBC test

6**Description**

C-Reactive Protein

Timepoint

Beginning and end of the intervention

Method of measurement

Agglutination method

7**Description**

Erythrocyte sedimentation rate (ESR)

Timepoint

Beginning and end of the intervention

Method of measurement

ESR device

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Capsule containing Ethanolic extract of Trachyspermum ammi at two dose of 250 mg per day for three consecutive months. These oral capsules of Ethanolic extract of Trachyspermum ammi will be prepared by a reputable pharmacist.

Category

Placebo

2**Description**

Control group: Placebo in capsules at two dose of 250 mg per day for three consecutive months. These placebo

oral capsules contain starch and will be prepared by a reputable pharmacist.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Liver and Digestive Clinic of Tohid Hospital, Sanandaj

Full name of responsible person

Dr Farshad Sheikh esmaeili

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Tohid Hospital, Tohid Blvd

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Sanandaj University of Medical Sciences

Full name of responsible person

Dr. Afshin Maleki

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Vice Chancellor for research of Kurdistan University of Medical Sciences, Pasharan Blvd, Sanandaj, Iran.

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Sanandaj 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

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Person responsible for general inquiries**Contact****Name of organization / entity**

Sanandaj University of Medical Sciences

Full name of responsible person

Dr Farshad Sheikhesmaeili

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Liver and Digestive

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Postal code**Person responsible for updating data****Contact****Name of organization / entity**

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Full name of responsible person

Pezhman Sharifi

Position

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Latest degree

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Other areas of specialty/work

Microbiology

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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

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

Not applicable

Data Dictionary

No - There is not a plan to make this available