Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

Efficacy of formula of Plantago major, and Rheum khorasanicum on clinical symptoms of patient with mild to moderate ulcerative colitis: a double blind randomized clinical trial

Protocol summary

Study aim
Determining the effect of the traditional product of Plantago major, and Rheum on the clinical symptoms of mild to moderate ulcerative colitis patients compared to placebo

Design
The clinical trial has a control group, double-blind, randomized, on 60 patients, randomly block in 4 blocks of four

Settings and conduct
Two groups of 30 patients in Kerman University of Medical Sciences, who were assigned randomly (random block) to the drug and placebo groups, follow-up and the desired response will be recorded at the beginning of the study, 3, 6 and 10 weeks.

Participants/Inclusion and exclusion criteria
Inclusion criteria: patients aged 18 to 60 with mild and moderate ulcerative colitis confirmed by Endoscopy and biopsy and with the diagnosis of gastroenterologist who signed the informed consent form have no exclusion criteria. Exclusion criteria: pregnancy or breastfeeding; use of antibiotics; NSAIDs OCPs or hormone therapy (in the last 2 weeks); suffering from disease complications; simultaneous suffering from serious diseases Liver, kidney, heart, cancer or celiac disease; smoking or drug addiction; suffering from other diseases Autoimmunity; simultaneous use of other traditional medicine and complementary medicine.

Intervention groups
Intervention group: consumes 2 capsules daily (1 in the morning and 1 in the evening) before meals. The capsule contains 2 parts of gourd extract and one part of rhubarb extract. Control group: consumes 2 capsules daily (1 in the morning and 1 in the evening). The capsule contains an equal volume of corn starch.

Main outcome variables
Partial Mayo score; Quality of Life; anxiety; depression; Stress

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150927024228N5**
Registration date: **2023-12-18, 1402/09/27**
Registration timing: **prospective**

Last update: **2023-12-18, 1402/09/27**
Update count: **0**

Registration date
2023-12-18, 1402/09/27

Registrant information

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Name of organization / entity
Kerman University Of Medical Sciences

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-03-10, 1402/12/20

Expected recruitment end date
2025-03-10, 1403/12/20

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of formula of Plantago major, and Rheum khorasanicum on clinical symptoms of patient with mild to moderate ulcerative colitis: a double blind randomized clinical trial

Public title

Investigation of the effect of Plantago major, and Rheum on colitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients aged 18 to 60 with mild and moderate ulcerative colitis confirmed by endoscopy and biopsy and diagnosed by a gastroenterologist who signed the informed consent form and did not meet the exclusion criteria.

Exclusion criteria:

Pregnancy or breastfeeding Taking antibiotics Taking herbal medicines, NSAIDs, OCPs or hormone therapy (in the last 2 weeks) Complications of the disease (such as massive bleeding requiring hospitalization or emergency surgery, fulminant colitis, peritonitis, toxic megacolon, obstructive stenosis), Suffering from liver, kidney, heart, cancer or celiac disease at the same time Addiction to smoking or drugs Suffering from other autoimmune diseases

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients with mild to moderate ulcerative colitis based on Partial Mayo score, and inclusion, and exclusion criteria, will be entered into Excel file (Microsoft Excel® software 2021), then randomly sorted through using "RAND", and "INDEX" formulas. Then, simple randomized patients, in the order of the list of excel, will be entered into the two groups of the study (drug, or placebo) according to the list of 6 blocks of 4 below (ABAB, BABA, ABBA, BAAB, AABB, BBAA) by a trained secretory, who is blinded in details of the study, based on randomized excel file.

Blinding (investigator's opinion)

Double blinded

Blinding description

Medicines and placebos are prepared by a traditional pharmacy specialist in the laboratory of the Iranian Faculty of Medicine, and after homogenization in terms of shape, smell, and color, they are provided to the researcher in completely similar packages.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Afzalipour Medical Education Center, Kerman University of Medical Sciences (Research Ethics Committ

Street address

Afzalipour hospital, Emam Khomeini highway

City

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Province

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7616913911

Approval date

2023-02-14, 1401/11/25

Ethics committee reference number

IR.KMU.AH.REC.1402.002

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

Partial Mayo score

Timepoint

At the beginning of the study, 3, 6 and 10 weeks

Method of measurement

Partial Mayo score questionnaire

Secondary outcomes

1

Description
Quality of life
Timepoint
At the beginning of the study, 3, 6 and 10 weeks
Method of measurement
Quality of life questionnaire (IBDQ-9)

2

Description
Anxiety, stress, and depression
Timepoint
At the beginning of the study, 3, 6 and 10 weeks
Method of measurement
DASS-21 questionnaire

Intervention groups

1

Description
Intervention group: consumes 2 capsules daily contain two parts of Plantago major extract, and one part of Rheum khorasanicum prepared by the pharmacist in the pharmaceutical laboratory (1 in the morning and 1 in the evening) with a glass of water and before meals and with an interval of one hour from the mesalamine drug.
Category
Treatment - Drugs

2

Description
Control group: consumes 2 capsules contain corn starch prepared by the pharmacist in the pharmaceutical laboratory daily (1 in the morning and 1 in the evening) with a glass of water and before meals and with an interval of one hour from the mesalamine drug.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Kerman University of Medical Sciences
Full name of responsible person
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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kerman 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
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Maryam Azimi
Position
Assistant Professor
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Person responsible for updating data

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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
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