Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

THE EFFECT OF IRANIAN TRADITIONAL MEDICINE PRODUCT(COLIT RELIEF) IN PREVENTION THE RELAPSE OF ULCERATIVE COLITIS PAITIENT

Protocol summary

Study aim

Determination of the Effect of ColiT Relife's Traditional Medicine on Preventing Recurrence of Symptoms in Patients with Ulcerative Colitis

Design

Patients in two divided groups receive both sulfasalazine 2.5 to 3 grams per day and folic acid tablets daily, and the prednisone treatment starts with TAPER in both groups of 10 mg per day. The first group with this 250 mg capsule regimen receives placebo once a day and the second group will receive the COLIT RELIF traditional medicine in the form of a capsule of 250 mg daily taken with food. Patients will receive it before and then every two weeks after the start The case study was conducted and clinical symptoms and the rate of recurrence in both groups were evaluated by filling in the SCCAI questionnaire.

Settings and conduct

Patients are given a gastroenterologist with a history, examination, colonoscopy, and histological examination of moderate to severe ulcerative colitis. They fit with the criteria for inclusion in the study, and after complete explanation of the study and obtaining personal consent Enter the study. Patients from medical clinics in Isfahan and Yazd were randomly divided into two groups by computer coding.

Participants/Inclusion and exclusion criteria

For patients, the diagnosis of infectious colitis is caused by Clostridium deficiency colitis, ischemic colitis, and drug dependent colitis. Patients with moderate to severe ulcerative colitis were diagnosed in the last month of the REMISSION phase. Failure to use other complementary and alternative therapies

Intervention groups

The intervention group also used Prednisolone and Cefalazine for the traditional medicine product COLIT RELIF.

Main outcome variables

1) The results of this study could be used to propose a new treatment protocol for ulcerative colitis. 2) Proof of scientific validity and efficacy of traditional Iranian medicine in the treatment of ulcerative colitis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171211037832N1**
Registration date: **2018-06-01, 1397/03/11**
Registration timing: **retrospective**

Last update: **2018-06-01, 1397/03/11**
Update count: **0**

Registration date

2018-06-01, 1397/03/11

Registrant information

Name

Fateme Rezayat

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 35 3724 0171

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f.rezayat@hsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-12-27, 1395/10/07

Expected recruitment end date

2017-03-19, 1395/12/29

Actual recruitment start date

2016-12-27, 1395/10/07

Actual recruitment end date

2017-10-23, 1396/08/01

Trial completion date

empty

Scientific title

THE EFFECT OF IRANIAN TRADITIONAL MEDICINE PRODUCT(COLIT RELIEF) IN PREVENTION THE RELAPSE OF ULCERATIVE COLITIS PAITIENT

Public title

The effect of traditional medicine COLIT RELIF in patients with ulcerative colitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

For patients, the diagnosis of infectious colitis is caused by Clostridium deficiency colitis, ischemic colitis, and drug dependent colitis. Patients with moderate to severe ulcerative colitis were diagnosed in the last month of the REMISSION phase. Failure to use other complementary and alternative therapies Completion of consent form in an informed manner

Exclusion criteria:

Pregnancy or breastfeeding The creation of a drug complication or allergy Dissatisfaction with the continuation of treatment

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size

Target sample size: **40**

Actual sample size reached: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

The research is experimental and experimental for 10 weeks for each patient. Patients were randomly assigned to two groups of 19 patients and 21 subjects divided into two groups: TAPERING, prednisolone 10 mg starting with 10 mg Sulfasalazine They also receive 2.5 to 3 grams per day. Our control group, along with its routine, received placebo in a 250 mg capsule once a day, and in the intervention group, traditional medicine COLIT RELIF was added to the patient's drug regimen in the form of a 250 mg capsule once a day.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The present study is three-blind. This blindness was done by the patient, the pharmacist, and the person who analyzed the data.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Yazd University of Medical Sciences

Street address

Central Organization of Yazd University of Medical Sciences. Shahid Bahonar Square

City

yazd

Province

Yazd

Postal code

8951737915

Approval date

2016-12-26, 1395/10/06

Ethics committee reference number

IR.SSU.REC.1395.195

Health conditions studied

1

Description of health condition studied

Ulcerative colitis

ICD-10 code

A06.1

ICD-10 code description

K51.0Ulcerative (chronic) pancolitisbackwash ileitis

Primary outcomes

1

Description

The results of this study could be used to propose a new treatment protocol for ulcerative colitis.

Timepoint

Effect of traditional medicine coliT relife before intervention and in weeks 2, 4, 6, 8 and 10 after intervention

Method of measurement

Regular medical check-ups

Secondary outcomes

1

Description

Proof of scientific validity and efficacy of traditional Iranian medicine in the treatment of ulcerative colitis

Timepoint

Before intervention and weeks 2, 4, and 6, 8 and 10 after intervention

Method of measurement

Regular patient visit and opinion form

Intervention groups

1

Description

Intervention group: Intervention group: The product of traditional medicine COLIT RELIF is presented in the form of a 250 mg capsule once a day along with food and also prednisolone starting at a dose of 10 mg plus sulfasalazine with a dose of 2.5 to 3 grams per day

Category

Treatment - Drugs

2

Description

Control group: Control group: Placebo in the form of a 250 mg capsule once a day as well as prednisolone started at a dose of 10 mg plus sulfasalazine with a dose of 2.5 to 3 grams per day...

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinics of Yazd and Isfahan

Full name of responsible person

Majid Emtiazy

Street address

Faculty of Traditional Medicine, Imam Khomeini street, Ardakan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Yazd 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

Yazd University of Medical Sciences

Full name of responsible person

Majid Emtiazy

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
The collected data includes a small fraction of the demographic characteristics and the mean clinical stability score. After being blinded, the analyst gets it.

When the data will become available and for how long
Get started two years after the results are published

To whom data/document is available
Researchers in the field of traditional medicine

Under which criteria data/document could be used
If comparing the doses of the drug between the intervention and the control, or comparing the quality of the data with the new data.

From where data/document is obtainable
Faculty of Ardakan Traditional Medicine

What processes are involved for a request to access data/document
In coordination with the Research Council and the Research and Student Vice-Chancellor of the Faculty of Traditional Medicine, Ardakan Branch, and after passing through its legal procedures.

Comments