

# 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)

##### Phone

+98 35 3724 0171

##### Email address

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

##### City

Ardakan

##### Province

Yazd

##### Postal code

8951737915

##### Phone

+98 35 2723 8917

##### Email

dr.emtiazy@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Yazd University of Medical Sciences

##### Full name of responsible person

Majid Emtiazy

##### Street address

Faculty of Traditional Medicine, Imam Khomeini street, Ardakan

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dr.emtiazy@yahoo.com

##### 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

##### Street address

Faculty of Traditional Medicine, Imam Khomeini street, Ardakan

##### City

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##### Province

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##### Postal code

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##### Phone

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##### Email

dr.emtiazy@yahoo.com

## Person responsible for scientific 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**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Majid Emtiazy

**Position**

Assistant Professor

**Latest degree**

Ph.D.

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dr.emtiazy@yahoo.com

## 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**