

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 2026

**Determining the effect of Montelukast in reducing disease recurrence in patients with moderate to severe ulcerative colitis during the period of gradual reduction of glucocorticoid dose.**

### Protocol summary

#### Study aim

Determining the effect of montelukast in reducing the recurrence of ulcerative colitis during the period of corticosteroid dose tapering

#### Design

Triple blinded , two arm parallel group randomised clinical trial

#### Settings and conduct

Patients with mod-sev ulcerative colitis who have entered to clinical remission after treatment of prednisolone 1 mg per kg(40-60 mg daily) and mesalazine 4 grams daily, with a full explanation of the process Continuing the maintenance drug treatment and accepting or not accepting the standard maintenance treatment of azathiopurine will be entered into the intervention group (receiving 10 mg Montelukast tablets daily) or the control group (receiving placebo tablets) for 16 weeks.patients will be monitored every two weeks in the IBD clinic by visits, questionnaires, inflammatory tests and calculation of the Modified Mayo score.The study will be triple-blind, in which the patient, the person evaluating the effects of the intervention, and the statistician will be unaware of the assignment of the groups.

#### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 18 to 75 years,moderate to severe ulcerative colitis,stage of clinical remission,Candidate for tapering corticosteroid dose,on high dose of corticosteroid 40-60 mg daily Exclusion criteria: age younger 18 or older 75y , any major organ disease or failure,patients receiving anti-TNF drugs or cyclosporine,patients with eosinophilic colitis , impaired level of consciousness,psychological diseases,Primary sclerosing cholangitis (PSC)

#### Intervention groups

Intervention group: prescribing Montelukast 10 mg tablets, Abidi Pharmaceutical Company, once daily for 16

weeks. Control group: Placebo drug administration for 16 weeks

#### Main outcome variables

Remaining in a state of clinical remission : Clinical recurrence as having symptoms and a Mayo score greater than or equal to 3

### General information

#### Reason for update

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20121212011738N3**

Registration date: **2022-10-13, 1401/07/21**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-10-13, 1401/07/21**

Update count: **0**

#### Registration date

2022-10-13, 1401/07/21

#### Registrant information

##### Name

Kurosh Masnadi Shirazi

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1334 7554

##### Email address

masnadik@tbzmed.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2022-10-12, 1401/07/20

**Expected recruitment end date**

2023-01-10, 1401/10/20

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Determining the effect of Montelukast in reducing disease recurrence in patients with moderate to severe ulcerative colitis during the period of gradual reduction of glucocorticoid dose.

**Public title**

The effect of Montelukast in reducing disease recurrence in patients with ulcerative colitis

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

All patients with moderate to severe ulcerative colitis  
Age 18 to 75 years Involvement beyond the rectosigmoid  
Treated with a high dose of corticosteroid 40-60 mg daily  
In the stage of clinical remission Candidate for tapering corticosteroid dose

**Exclusion criteria:**

Age less than 18 Age more than 75 Severely ill patients need hospitalization and special measures Pregnant or lactating women Suffering from systemic diseases including heart, kidney, lung or liver failure Patients with impaired level of consciousness patients with Primary sclerosing cholangitis (PSC) patients with eosinophilic colitis patients with psychological diseases patients receiving anti-TNF drugs or cyclosporine

**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
- Data and Safety Monitoring Board

**Sample size**

Target sample size: **160**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Simple randomization will be done using Graphpad software. The randomization unit is individual. So that the graphpad software will present the letter A (for the intervention group) and the letter B for the control group for two groups of our patients. This list will be in the hands of the secretary of the department and until the end of the study, only he will know about the allocation

of people. Patients will be directed to one of the two groups A or B based on the list by the secretary of the department according to their visit to the clinic. The department secretary will not be involved in other research areas.

**Blinding (investigator's opinion)**

Triple blinded

**Blinding description**

The study will be triple-blind, in which the patient, the person evaluating the effects of the intervention, and the statistician will be unaware of the assignment of the groups. For blinding, the placebo will be prepared in the same packaging as the original drug, and the letters A and B will be used by the secretary of the department for the cans of drugs and placebo. And the contents of the cans will remain secret until the end of the study and only the department secretary will know about the contents of cans A and B.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Tabriz University of Medical Sciences

**Street address**

Tabriz University of Medical Sciences, Golgasht Street, Tabriz

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166614766

**Approval date**

2022-09-10, 1401/06/19

**Ethics committee reference number**

IR.TBZMED.REC.1401.496

**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

Remaining in a state of clinical remission

#### Timepoint

Every 2 weeks from the start of tapering the dose of corticosteroids until 6 weeks after complete cessation of corticosteroids

#### Method of measurement

History, physical examination, questionnaire , laboratory tests(ESR,CRP,CBC, Fecal calprotectin) , modified Mayo score

### 2

#### Description

Clinical recurrence as having symptoms and a Mayo score greater than or equal to 3

#### Timepoint

Every 2 weeks from the start of tapering the dose of corticosteroids until 6 weeks after complete cessation of corticosteroids

#### Method of measurement

History, physical examination, questionnaire , laboratory tests(ESR,CRP,CBC, Fecal calprotectin) , modified Mayo score

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: prescribing Montelukast 10 mg tablets, Abidi Pharmaceutical Company, once daily for 16 weeks.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Placebo drug administration for 16 weeks

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Clinics of Sheikhorrais and Emam-reza hospital

##### Full name of responsible person

Masnadi shirazi Kurosh

##### Street address

Golgasht St. , Emam-reza hospital

#### City

Tabriz

#### Province

East Azarbaijan

#### Postal code

3333456787

#### Phone

+98 41 3334 7054

#### Email

mndiba59@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Full name of responsible person

Dr. Mohammad Reza Rashidi

##### Street address

Vice chancellor for Research of Tabriz University of Medical Sciences,Tabriz University of Medical Sciences, Golgasht Street, Tabriz

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

۳۳۳۳۴۵۶۶۷۷

##### Phone

+98 41 3334 7054

##### Email

mndiba59@gmail.com

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

##### Full name of responsible person

Nezamdiba Mehran

##### Position

Gastrointestinal fellowship

**Latest degree**

Specialist

**Other areas of specialty/work**

Internal Medicine

**Street address**

No.41 , Gulshan Boulevard, Tejalai Square

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

۳۳۳۳۶۶۴۵۵۱

**Phone**

+98 41 3347 8021

**Email**

mndiba59@gmail.com

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

Tabriz University of Medical Sciences

**Full name of responsible person**

Kurosh Masnadi Shirazi

**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Internal Medicine

**Street address**

Gastrointestinal Research Center , Emamreza hospital, Golgasht st.

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

۳۳۳۳۴۵۶۰۶۹

**Phone**

+98 41 1334 7554

**Fax**

+98 41 1334 7554

**Email**

masnadik@tbzmed.ac.ir

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

Tabriz University of Medical Sciences

**Full name of responsible person**

Nezamdiba Mehran

**Position**

Gastrointestinal fellowship

**Latest degree**

Specialist

**Other areas of specialty/work**

Internal Medicine

**Street address**

No.41 , Gulshan Boulevard, Tejalai Square

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

۳۳۳۳۶۶۴۵۵۱

**Phone**

+98 41 3347 8021

**Email**

mndiba59@gmail.com

**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**

Not applicable

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable