

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### Effect of Maqliasa - a traditional Persian medicine formulation on ulcerative colitis: A pilot clinical study

#### Protocol summary

##### Summary

The study is accomplished as a pilot before-after clinical trial without control group. The goals of the study are determination of effect of Maqliasa on severity of symptoms in ulcerative colitis, probable side effects and determination of conditions for a double blind RCT. Study population is the admitted outpatients to GI clinic of Rasoul Akram hospital and Tehran university of medical sciences clinic of traditional medicine. The diagnosis is done via colonoscopy by gastroenterologist. Inclusion criteria are age between 18 to 70 y/o, no history of peptic ulcer, no history of toxic megacolon, and no history of colon cancer. Exclusion criteria are: appearance of peptic ulcer manifestations and emergence of severe drug complications. The patients fill the written consent form. Also, conditions of the research will be explained. The patients undergo a 28-day trial with the drug "Maqliasa". Three visits are accomplished for each patient; First admission, 14 days later and 28 days later. At the first admission, after a disease evaluation by ulcerative colitis disease activity index, the needed drug is rendered to the patients for 14 days. At the 2nd visit, changes in the manifestations will be evaluated by the above-mentioned index. Then, the rest of the drug will be rendered. At the third visit changes will be evaluated again for the third time. After data gathering, analysis with SPSS will be done.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017042719489N2**  
Registration date: **2017-07-09, 1396/04/18**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-07-09, 1396/04/18

##### Registrant information

###### Name

Meysam Shirzad

###### Name of organization / entity

School of traditional medicine, Tehran university of medical sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8897 4535

###### Email address

shirzad@tums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Barij Essence Pharmaceutical Company

##### Expected recruitment start date

2017-06-11, 1396/03/21

##### Expected recruitment end date

2017-07-23, 1396/05/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of Maqliasa - a traditional Persian medicine formulation on ulcerative colitis: A pilot clinical study

##### Public title

Effect of Maqliasa capsule on ulcerative colitis

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: 1- The study is accomplished in

patients suffer from ulcerative colitis confirmed by colonoscopy 2- Age limit between 18 to 70 y/o 3- No pregnancy 4- No breastfeeding 5- No history of peptic ulcer 6- No history of toxic megacolon 7- No history of colon cancer Exclusion criteria: 1- Appearance of peptic ulcer manifestations 2- Emergence of severe drug complications

#### **Age**

From **18 years** old to **70 years** old

#### **Gender**

Both

#### **Phase**

2

#### **Groups that have been masked**

*No information*

#### **Sample size**

Target sample size: **15**

#### **Randomization (investigator's opinion)**

N/A

#### **Randomization description**

#### **Blinding (investigator's opinion)**

Not blinded

#### **Blinding description**

#### **Placebo**

Not used

#### **Assignment**

Single

#### **Other design features**

### **Secondary Ids**

empty

### **Ethics committees**

#### **1**

#### **Ethics committee**

##### **Name of ethics committee**

Tehran University of Medical Sciences

##### **Street address**

Qods St, Keshvarz Blv

##### **City**

Tehran

##### **Postal code**

#### **Approval date**

2017-06-10, 1396/03/20

#### **Ethics committee reference number**

IR.TUMS.VCR.REC.1396.2559

### **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**

Diarrhea (Number of daily stools)

#### **Timepoint**

Onset of intervention, 14 and 28 days later

#### **Method of measurement**

Patient statements

#### **2**

#### **Description**

Nocturnal diarrhea

#### **Timepoint**

Onset of intervention, 14 and 28 days later

#### **Method of measurement**

Patient statements

#### **3**

#### **Description**

Fecal incontinence

#### **Timepoint**

Onset of intervention, 14 and 28 days later

#### **Method of measurement**

Patient statements

#### **4**

#### **Description**

Abdominal pain or cramping

#### **Timepoint**

Onset of intervention, 14 and 28 days later

#### **Method of measurement**

Patient statements

#### **5**

#### **Description**

General well-being

#### **Timepoint**

Onset of intervention, 14 and 28 days later

#### **Method of measurement**

Patient statements

#### **6**

#### **Description**

Abdominal tenderness

#### **Timepoint**

Onset of intervention, 14 and 28 days later

#### **Method of measurement**

Physical exam

#### **7**

#### **Description**

Need for anti-diarrhea drugs

#### **Timepoint**

Onset of intervention, 14 and 28 days later

#### **Method of measurement**

Patient statements

## Secondary outcomes

1

### Description

Adverse drug reactions

### Timepoint

Days 14th and 28th

### Method of measurement

Patient statements

## Intervention groups

1

### Description

Herbal product capsules called "Maqliasa" -2 capsules three times daily orally for intervention group -There is no control group -Duration of intervention: 28 days - Manufacturer: Barij Essence Pharmaceutical Company

### Category

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Rasoul Akram general hospital, GI clinic

#### Full name of responsible person

Dr. Shahram Agah

#### Street address

Niayesh St., Satarkhan St.

#### City

Tehran

2

### Recruitment center

#### Name of recruitment center

Tehran university of medical sciences clinic of traditional medicine (Ahmadie)

#### Full name of responsible person

Dr. Meysam Shirzad

#### Street address

No. 27, Sarparast St., Taleqani Ave.

#### City

Tehran

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Barij Essence Pharmaceutical Co.

#### Full name of responsible person

Mrs. Laleh Hejazi

### Street address

P.O. Box: 1178, Mashad Ardehal

### City

Kashan

### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

Barij Essence Pharmaceutical Co.

### Proportion provided by this source

100

### Public or private sector

*empty*

### Domestic or foreign origin

*empty*

### Category of foreign source of funding

*empty*

### Country of origin

### Type of organization providing the funding

*empty*

## Person responsible for general inquiries

### Contact

#### Name of organization / entity

Alborz university of medical sciences

#### Full name of responsible person

Dr. Mohammadmahdi Ahmadian-Attari

#### Position

PhD in Traditional Pharmacy

#### Other areas of specialty/work

#### Street address

No. 132, Marzdaran St.

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Tehran University of Medical Sciences

#### Full name of responsible person

Dr. Meysam Shirzad

#### Position

Assistant professor- Specialist in traditional medicine

#### Other areas of specialty/work

#### Street address

No.27, Sarparast Ave., Taleqani St., Tehran, Iran

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Meysam Shirzad MD, PhD

**Position**

Assistant Professor- Specialist in traditional medicine

**Other areas of specialty/work**

**Street address**

No.27, Sarparast Ave., Taleqani St.

**City**

Tehran

**Postal code**

**Phone**

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*