

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 2026

### The evaluation of Nano-micelle curcumin efficacy in patients with mild to moderate ulcerative colitis

#### Protocol summary

##### Summary

This is a double blind controlled clinical trial in which patient aged between 18-70 years old with mild to moderate UC, in spite of maximum mesalamine treatment, divided in two groups of corchomin+mesalamine and placebo+mesalamine group, which is taken twice a day after breakfast and lunch. The diagnosis of UC was confirmed by endoscopy. Sinacorchine is a soft gelatinous capsule containing 40 and 80 milligram of nanomiscles of corchomine (minoo-tehran factory). Placebo is a soft gelatinous capsule without efficient corchomin products. At the beginning of the study all patients will be taught about appropriate diet and lifestyle. Patients will be visited every month for delivery of previous drug packages and handing over new capsules. Also taking pills will be followed every week with phone calls.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017071435080N1**

Registration date: **2017-09-06, 1396/06/15**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-09-06, 1396/06/15

##### Registrant information

##### Name

Mehdi Moosavian

##### Name of organization / entity

Tehran university of medical science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6658 1612

##### Email address

mmoosavian@razi.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Tehran University of Medical Sciences & Exir Nano Sina company

##### Expected recruitment start date

2017-04-21, 1396/02/01

##### Expected recruitment end date

2017-08-22, 1396/05/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The evaluation of Nano-micelle curcumin efficacy in patients with mild to moderate ulcerative colitis

##### Public title

Therapeutic effect of curcumin on ulcerative colitis

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

It's a randomized double blind controlled trial in patients with mild to moderate ulcerative colitis which is under treatment with maximum dose of mesalamine. Patients aged between 18-70 years old with UC, which has been approved by endoscopy, will be enrolled. Mild to moderate active UC based on "simple clinical colitisactivity index (SCCAI) score" will be defined as <5 and <12 score, respectively. subjects with history of current or in past 12 weeks use of steroids, taking anti-TNF or cyclosporine, has Hgb<10 mg/dl or hematologic abnormalities including leukopenia, thrombocytopenia,

those with impaired renal, coagulation or liver tests, subjects with positive C diff infection, pregnant patients, presence of active sepsis and nurses will be excluded from the study.

#### **Age**

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

#### **Gender**

Both

#### **Phase**

1-2

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

*No information*

#### **Sample size**

Target sample size: **40**

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

Randomized

#### **Randomization description**

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

Double blinded

#### **Blinding description**

#### **Placebo**

Used

#### **Assignment**

Parallel

#### **Other design features**

### **Secondary Ids**

empty

### **Ethics committees**

#### 1

##### **Ethics committee**

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

tehran university of medical science

###### **Street address**

city deivision 6, poor sina street

###### **City**

Tehran

###### **Postal code**

##### **Approval date**

2017-05-31, 1396/03/10

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

IR.TUMS.IKHC.REC.1396.2599

### **Health conditions studied**

#### 1

##### **Description of health condition studied**

ulcerative colitis

##### **ICD-10 code**

##### **ICD-10 code description**

### **Primary outcomes**

#### 1

##### **Description**

Simple clinical colitisactivity index (SCCAI) score

##### **Timepoint**

At the begining of study, 8 week after treatment

##### **Method of measurement**

questionairre

#### 2

##### **Description**

Stool calprotectin

##### **Timepoint**

At the begining of study, 8 week after treatment

##### **Method of measurement**

lab test

#### 3

##### **Description**

Mayo score

##### **Timepoint**

at the begining of study, 8 week after treatment

##### **Method of measurement**

questionairre

#### 4

##### **Description**

Serum cytokins(IFN- $\gamma$ , IL- 12, IL-4, IL-10, TGF- $\beta$  , IL-17)

##### **Timepoint**

At the begining of study, 8 week after treatment

##### **Method of measurement**

lab test

#### 5

##### **Description**

Grading scale for histological assessment of inflammation in ulcerative colitis

##### **Timepoint**

at the begining of study, 8 week after treatment

##### **Method of measurement**

biopsy and lab test

#### 6

##### **Description**

Self assessment scales for evaluating mood characteristics pre and post intervention

##### **Timepoint**

at the begining of study, 8 week after treatment

##### **Method of measurement**

questionairre

#### 7

##### **Description**

CRP

##### **Timepoint**

at the begining of study, 8 week after treatment

##### **Method of measurement**

lab test

## Secondary outcomes

1

### Description

Hgb

### Timepoint

At onset of study, end of study (8 week after treatment)

### Method of measurement

lab test

2

### Description

Quantity of Bacteroides family and clostridium

### Timepoint

At onset of study, end of study (8 week after treatment)

### Method of measurement

lab test

## Intervention groups

1

### Description

cap corchomin 80 mg twice a day for three months

### Category

Treatment - Drugs

2

### Description

Placebo cap twice daily

### Category

Placebo

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Emam Khomayni Hospital

#### Full name of responsible person

Mehdi Moosavian

#### Street address

end of Keshavarz Blv

#### City

Tehran

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

EXIR nano sina

#### Full name of responsible person

Mahnaz Ghomy

#### Street address

Fatemi sq , Shahid gomnam street, jahan mehr street , fathi shaghaghy street , Num 94

### City

Tehran

### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

EXIR nano sina

### Proportion provided by this source

### 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

2

### Sponsor

#### Name of organization / entity

Tehran university Of medical science

#### Full name of responsible person

Masoud Yoonesian

#### Street address

Tehran university central building, cross Keshavarz Blv and Ghods street

#### City

Tehran

### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

Tehran university Of medical science

### Proportion provided by this source

### 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

Tehran university of medical science

#### Full name of responsible person

Mehdi Moosavian

#### Position

Adult Gastrointestinal and Hepatologist

#### Other areas of specialty/work

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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**Web page address**

## 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*