Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The evaluaation of Nano-micelle curcumin efficacy in patients whit mild to moderate ulcerative culities

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. Sinacorchomine is a soft gelatinous capsule containing 40 and 80 milligram of nanomisceles 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

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Mehdi Moosavian
Name of organization / entity
Tehran university of medical science
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Iran (Islamic Republic of)
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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 evaluaation of Nano-micelle curcumin efficacy in patients whit mild to moderate ulcerative culities

Public title

Therapeutic effect of curcumin on ulcerative culities

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 devision 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-γ, IL- 12, IL-4, IL-10, TGF-β , 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 inflamation 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 chracteristcs 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 Bacteroidous family and colestridium
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 Khomainy 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 0f 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 0f 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

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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