# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

20 Oct 2020

## Evaluation of SinaCurcumin as a complementary therapy in mild to moderate COVID-19: An open label non-randomized clinical trial

## Protocol summary

**Study aim**

Evaluation of the SinaCurcumin efficacy as a supplement for treatment of mild to moderate COVID-19

**Design**

This is a non-randomized open label, parallel group clinical trial on 60 patients with mild to moderate covid-19 (30 patients in treatment group and 30 patients in control).

**Settings and conduct**

This study will perform on 60 patients with clinical or laboratory diagnosis of mild to moderate covid-19 who refer to Sharif Clinic, Mashhad, Iran. They whether will received two sinacurcumin 40mg capsule twice daily for 2 weeks and then one capsule 40mg twice daily for 2weeks in treatment group or standard measures in control group.

**Participants/Inclusion and exclusion criteria**

Inclusion criteria: Laboratory or radiologic or clinical diagnosis of mild to moderate COVID-19, age between 18-65y, sign of the written consent Exclusion criteria: more than 7d from the beginning of the symptoms, pregnancy or lactation, history of allergy to curcumin or turmeric, smoking (more than 5 cigarettes per day), adverse drug reaction occurrence, past medical diseases (e.g. kidney, hepatic, heart failure, complicated heart or brain disease, diabetes, chronic lung disease, malignancies, endocrine diseases, any immune system dysfunction, history of gallbladder, or active GI ulcer)

**Intervention groups**

Treatment group: two capsule Sinacurcumin 40mg twice daily for 2 weeks, one capsule 40mg twice daily for two weeks Control group: no intervention

**Main outcome variables**

Primary endpoints of the study are rates of treatment response and adverse drug reactions. Secondary endpoints are duration of hospitalization and patients' clinical outcomes.

## General information

**Reason for update**

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT20200408046990N1**
Registration date: **2020-04-18, 1399/01/30**
Registration timing: **prospective**

Last update: **2020-04-18, 1399/01/30**
Update count: **0**

**Registration date**

2020-04-18, 1399/01/30

**Registrant information**

**Name**

Sepideh Elyasi

**Name of organization / entity**

**Country**

Iran (Islamic Republic of)

**Phone**

+98 51 3180 1588

**Email address**

elyasis@mums.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

**Expected recruitment start date**

2020-05-19, 1399/02/30

**Expected recruitment end date**

2020-09-20, 1399/06/30

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Evaluation of SinaCurcumin as a complementary therapy in mild to moderate COVID-19: An open label non-randomized clinical trial

**Public title**
Evaluation of SinaCurcumin capsule efficacy as an supplement therapy for mild to moderate COVID-19 in Mashhad
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
laboratory or radiologic or clinical diagnosis of mild to moderate COVID-19 age between 18-65y sign of the written consent Not simultaneous participating in other clinical trials
**Exclusion criteria:**
more than 7d from the beginning of the symptoms pregnancy or lactation history of allergy to curcumin or turmeric smoking (more than 5 cigarettes per day) complicated concomitant bacterial infection adverse drug reaction occurrence SaO2<90% past medical diseases (e.g. kidney, hepatic, heart failure, complicated heart or brain disease, diabetes, chronic lung disease, malignancies, endocrine diseases, any immune system dysfunction like AIDS) history of gallbladder history of active GI ulcer
**Age**
From **18 years** old to **65 years** old
**Gender**
Both

**Phase**
3
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **60**
**Randomization (investigator's opinion)**
Not randomized
**Randomization description**
**Blinding (investigator's opinion)**
Not blinded
**Blinding description**
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics committee of Mashhad University of Medical Sciences
**Street address**
Daneshgah street; Qureshi Building
**City**
Mashhad
**Province**
Razavi Khorasan
**Postal code**
1394491388
**Approval date**
2020-04-08, 1399/01/20
**Ethics committee reference number**
IR.MUMS.REC.1399.054

## Health conditions studied

### 1

**Description of health condition studied**
COVID-19 pneumonia
**ICD-10 code**
U07.1
**ICD-10 code description**
COVID-19, virus identified

## Primary outcomes

### 1

**Description**
fever
**Timepoint**
daily
**Method of measurement**
thermometer

### 2

**Description**
clinical response to treatment (including improvement of cough, myalgia, headache, Olfactory and taste disorders)
**Timepoint**
daily
**Method of measurement**
Based on clinical, paraclinical and laboratory findings

### 3

**Description**
drug adverse reaction
**Timepoint**
daily
**Method of measurement**
patient interview and file

### 4

**Description**
radiologic response
**Timepoint**
one month after the beginning of the treatment
**Method of measurement**
lung HRCT

## Secondary outcomes

### 1

**Description**
length of hospital stay
**Timepoint**
at the end of treatment course
**Method of measurement**
patient file

### 2

**Description**
patient clinical outcome
**Timepoint**
at the end of the treatment
**Method of measurement**
patient file

## Intervention groups

### 1

**Description**
Intervention group: nanocurcumin capsule 40mg, two capsule twice daily for two weeks then 1 capsule twice daily for 2 weeks
**Category**
Treatment - Drugs

### 2

**Description**
Control group:all standard measures will be performed for patient.
**Category**
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Sharif Clinic
**Full name of responsible person**
Sepideh Elyasi
**Street address**
Faculty of Pharmacy, Ferdowsi University, Vakilabad Boulevard
**City**
Mashhad
**Province**
Razavi Khorasan
**Postal code**
17871 91886
**Phone**
+98 51 3180 1588
**Email**
elyasis@mums.ac.ir

## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Mashhad University of Medical Sciences
**Full name of responsible person**
Mohsen Tafaghodi
**Street address**
Faculty of Pharmacy, Ferdowsi University, Vakilabad Boulevard
**City**
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17871 91886
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**Email**
tafaghodim@mums.ac.ir
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Mashhad University of Medical Sciences
**Proportion provided by this source**
10
**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

### 2

**Sponsor**
**Name of organization / entity**
Exir Nano Sina Pharmaceutical Company
**Full name of responsible person**
Mahmoud Reza Jafari
**Street address**
Jahanmehr Aven.,Tehran
**City**
Tehran
**Province**
Tehran
**Postal code**
17871 91886
**Phone**
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**Email**
jafarimr@mums.ac.ir
**Grant name**
**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Exir Nano Sina Pharmaceutical Company
**Proportion provided by this source**
90
**Public or private sector**
Private
**Domestic or foreign origin**
Domestic
**Category of foreign source of funding**
*empty*
**Country of origin**
**Type of organization providing the funding**
Industry

## Person responsible for general inquiries

**Contact**
**Name of organization / entity**
Mashhad University of Medical Sciences
**Full name of responsible person**
Sepideh Elyasi
**Position**
Associate Professor
**Latest degree**
Specialist
**Other areas of specialty/work**
Medical Pharmacy
**Street address**
Vakilabad Boulevard; Ferdowsi University; Faculty of Pharmacy
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## Person responsible for scientific inquiries

**Contact**
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Mashhad University of Medical Sciences
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Associate Professor
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Medical Pharmacy
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elyasis@mums.ac.ir

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Mashhad University of Medical Sciences
**Full name of responsible person**
Sepideh Elyasi
**Position**
Associate Professor
**Latest degree**
Specialist
**Other areas of specialty/work**
Medical Pharmacy
**Street address**
Faculty of Pharmacy, Ferdosi University, Vakilabad Aven.
**City**
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**Province**
North Khorasan
**Postal code**
17871 91886
**Phone**
+98 51 3180 1588
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elyasis@mums.ac.ir

## 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**
No - There is not a plan to make this available
**Informed Consent Form**
No - There is not a plan to make this available
**Clinical Study Report**
Yes - There is a plan to make this available
**Analytic Code**
No - There is not a plan to make this available
**Data Dictionary**
No - There is not a plan to make this available
**Title and more details about the data/document**
The findings will be published in an article. Study protocol and statistical analysis will be used for article publication.
**When the data will become available and for how long**
One year after the end of the study it will be published and available in databases.
**To whom data/document is available**

If the funding sponsor allowed, the findings will be available for researchers, clinicians, and scientific centers.

**Under which criteria data/document could be used**

The other researchers can use our findings in their review articles and meta analysis.

**From where data/document is obtainable**

For this purpose, you can contact with Sepideh Elyasi, at Clinical Pharmacy Department, School of Pharmacy, Vakil Abad Aven., Mashhad, Iran. Email: elyasis@mums.ac.ir

**What processes are involved for a request to access data/document**

After receiving the query, dependent on the requested data, the scientific responsible person of the study will response to the query in coordinate with the sponsor within 2 weeks

**Comments**