Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 May 2026

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
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Razavi Khorasan
Postal code
17871 91886
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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
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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
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Province
Tehran
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17871 91886
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+98 21 8822 3260
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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
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Vakilabad Boulevard; Ferdowsi University; Faculty of Pharmacy
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Person responsible for updating data

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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