

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 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

Mashhad

Province

Razavi Khorasan

Postal code

17871 91886

Phone

+98 51 3180 1337

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

+98 21 8822 3260

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

City

Mashhad

Province

Razavi Khorasan

Postal code

17871 91886

Phone

+98 51 3180 1588

Email

elyasis@mums.ac.ir

Person responsible for scientific 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

Faculty of Pharmacy, Ferdosi University, Vakilabad Aven.

City

Mashhad

Province

Razavi Khorasan

Postal code

17871 91886

Phone

+98 51 3180 1588

Email

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

Mashhad

Province

North Khorasan

Postal code

17871 91886

Phone

+98 51 3180 1588

Email

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