

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jan 2021

### Investigating the effect of curcumin-piperine supplementation in accelerating the recovery period of patients with covid-19

#### Protocol summary

Registration timing: **registered\_while\_recruiting**

#### Study aim

Investigating the effect of curcumin supplementation on improving inflammatory parameters and regulating coagulation factors in patients with covid-19

Last update: **2020-08-10, 1399/05/20**

Update count: **0**

#### Registration date

2020-08-10, 1399/05/20

#### Design

The study is a phase-3 randomized double-blind clinical trial, in which people with covid-19 will be divided into two groups with 30 people taking curcumin supplements and 30 people taking placebo. Random allocation software will be used to randomize samples into two treatment and placebo groups.

#### Registrant information

##### Name

Majid Teremmahi Ardestani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 76 3366 6367

##### Email address

majidardestani50@gmail.com

#### Settings and conduct

This study is a phase-3 double-blind clinical trial. People with covid-19 who will refer to the Prophet's hospital will be selected. Random Allocation software will be used to randomize the sample to two treatment groups and placebo in Random Allocation software. Capsules will be stored and given in similar packages (with A and B marks) to patients by an out-of-study person.

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Participants/Inclusion and exclusion criteria

Inclusion criteria: Covid-19 approved patients with PCR or CT-SCAN testing, satisfaction to participation, Aged 18-70 years. Exclusion criteria: history of susceptibility to jaundice, biliary disorders, cardiovascular disorders and recipients of anticoagulants.

#### Expected recruitment start date

2020-08-05, 1399/05/15

#### Expected recruitment end date

2020-08-20, 1399/05/30

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Intervention groups

- 1- Patients receiving curcumin supplementation
- 2- Patients receiving placebo

#### Trial completion date

empty

#### Main outcome variables

ct-scan findings; Hospitalization duration; CBC; LDH; PT; PTT; D-DIMER; BUN / CR.

#### Scientific title

Investigating the effect of curcumin-piperine supplementation in accelerating the recovery period of patients with covid-19

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200514047445N1**

Registration date: **2020-08-10, 1399/05/20**

##### Public title

Evaluation of the effect of curcumin in improving patients with covid -19

## Purpose

Supportive

## Inclusion/Exclusion criteria

### Inclusion criteria:

Satisfaction to participate in the study Aged 18-70 years  
Real Time PCR or CT-SCAN positive test

### Exclusion criteria:

Bile problem Curcumin allergy problems Cardiovascular diseases Use of anticoagulants

## Age

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

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant
- Investigator
- Data analyser

## Sample size

Target sample size: **60**

More than 1 sample in each individual

Number of samples in each individual: **2**

Two blood samples are taken from patients one week apart

## Randomization (investigator's opinion)

Randomized

## Randomization description

Random Allocation software was used to randomize the sample into two treatment and placebo groups. Output of mentioned software includes a table that shows the number of each patient is located in each group (intervention or placebo).

## Blinding (investigator's opinion)

Double blinded

## Blinding description

Patients and researchers are unaware of the type of medication given to the patient. Drugs in similar capsules stored in packages with A and B marks are given to patients by a neutral person (an out-of-study person).

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Hormozgan University of Medical Sciences

##### Street address

Payambar azam hospital complex-technology and research vice- chancellor

#### City

Bandar Abbas

#### Province

Hormozgan

#### Postal code

-

#### Approval date

2020-06-15, 1399/03/26

#### Ethics committee reference number

IR.HUMS.REC.1399.187

## Health conditions studied

### 1

#### Description of health condition studied

covid-19

#### ICD-10 code

U07.2

#### ICD-10 code description

virus not identified

## Primary outcomes

### 1

#### Description

Lung CT-SCAN

#### Timepoint

First admission and one week after admission

#### Method of measurement

CT-SCAN IMAGING

### 2

#### Description

Duration of hospitalization

#### Timepoint

Patient discharge time or death

#### Method of measurement

patient medical records

### 3

#### Description

Complete blood count

#### Timepoint

First admission and one week after admission

#### Method of measurement

cell counter

### 4

#### Description

C-Reactive protein

#### Timepoint

First admission and one week after admission

#### Method of measurement

Agglutination method

## 5

### **Description**

LDH

### **Timepoint**

First admission and one week after admission

### **Method of measurement**

Spectrophotometric assay

## 6

### **Description**

Erythrocyte sedimentation rate

### **Timepoint**

First admission and one week after admission

### **Method of measurement**

sediment analyzer

## 7

### **Description**

prothrombine time

### **Timepoint**

First admission and one week after admission

### **Method of measurement**

coagulometer

## 8

### **Description**

partial thromboplastine time

### **Timepoint**

First admission and one week after admission

### **Method of measurement**

coagulometer

## 9

### **Description**

D-Dimer test

### **Timepoint**

First admission and one week after admission

### **Method of measurement**

nephelometry

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: patients are given 3 curcumin capsules(500mg) daily after three meals

#### **Category**

Treatment - Other

### 2

#### **Description**

Control group: Take 3 placebo (500 mg of lactose) daily for 3 weeks for 2 weeks.

## **Category**

Placebo

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Payambar-azam hospital

##### **Full name of responsible person**

Majid Teremmahi Ardestani

##### **Street address**

Bandar Abbas - Imam Khomeini St. - Jomhuri Eslami  
Boulevard - Payambar Azam Hospital

##### **City**

Bandar Abbas

##### **Province**

Hormozgan

##### **Postal code**

7916839319

##### **Phone**

+98 76 3366 6367

##### **Email**

majidardestani50@gmail.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Bandare-abbas University of Medical Sciences

##### **Full name of responsible person**

Timur Agha Molai

##### **Street address**

Immam Khomeini Ave, Jomhuri blvd

##### **City**

Bandar Abbas

##### **Province**

Hormozgan

##### **Postal code**

7916839319

##### **Phone**

+98 76 3333 7192

##### **Email**

research@hums.ac.ir

#### **Grant name**

#### **Grant code / Reference number**

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

Yes

#### **Title of funding source**

Bandare-abbas University of Medical Sciences

#### **Proportion provided by this source**

100

#### **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

## Person responsible for general inquiries

### Contact

**Name of organization / entity**  
Bandare-abbas University of Medical Sciences  
**Full name of responsible person**  
Majid Teremmahi Ardestani  
**Position**  
Associate professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Hematology  
**Street address**  
Immam Khomeini Ave- Sout Resalat blvd  
**City**  
Bandar Abbas  
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**Email**  
majidardestani50@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Bandare-abbas University of Medical Sciences  
**Full name of responsible person**  
Majid Teremmahi Ardestani  
**Position**  
Associate professor  
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## Person responsible for updating data

### Contact

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Bandare-abbas University of Medical Sciences  
**Full name of responsible person**  
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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

No - There is not 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

Unrecognizable data files related to the main consequence will be shared.

### When the data will become available and for how long

6 month

### To whom data/document is available

Researchers and therapists

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

Similar studies

### From where data/document is obtainable

Dr majid teremmahi Ardestani

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

The information will be sent after receiving the request.

### Comments