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

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

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.

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.

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.

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

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

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200514047445N1**
Registration date: **2020-08-10, 1399/05/20**
Registration timing: **registered_while_recruiting**

Last update: **2020-08-10, 1399/05/20**
Update count: **0**

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

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

Recruitment status
Recruitment complete

Funding source

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

Trial completion date
empty

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

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- chancellery
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
nephlometery

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
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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

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Immam Khomeini Ave- Sout Resalat blvd

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Person responsible for scientific inquiries

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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

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