

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Oct 2020

Effect of curcumin-piperine supplementation on disease duration, severity and clinical signs, and inflammatory factors in patients with coronavirus(COVID-19): A randomized, double-blind, placebo-controlled clinical trial study

Protocol summary

Study aim

Determination of the effect of curcumin-piperine supplementation on disease duration, severity and clinical signs, and inflammatory factors in patients with coronavirus(COVID-19): A randomized, double-blind, placebo-controlled clinical trial study

Design

This is a randomized, placebo-controlled, double-blind parallel-group clinical trial. one hundred participants will randomly allocated to receive curcumin-piperine supplement per day (n = 50) or placebo (n = 50).

Settings and conduct

In this study, patients with coronavirus will recruited from hospitals of Isfahan University of Medical Sciences. Subjects will stratified according to gender. Random assignment will done by the use of table of random numbers. The enrolling participants, and assigning participants to the groups will carried out by a relevant specialist. The curcumin-piperine supplement and its placebos will be packed in similar boxes, and the researcher and the patients will not be aware of the content of the pack until the end of the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Tendency to participate in the study; People aged 18-65 years; Diagnosis of Covid-19 based on clinical findings and imaging findings (Chest X Ray), CT scan or PCR Exclusion criteria: Age less than 20 and more than 75 years; Taking warfarin; Sensitivity to plant products such as turmeric and pepper

Intervention groups

Individuals will randomly assigned to two groups to receive 1000 mg/day curcumin-piperine supplement or placebo for 12 weeks.

Main outcome variables

CT of the chest, body temperature, length of hospital stay, hs-CRP, ESR, ALT, AST, LDH, BUN, creatinine, CBC,

blood oxidative stress indices (SOD, MDA, TAC), Albumin, Severity of the disease, severity and number of coughs

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20121216011763N46**

Registration date: **2020-05-04, 1399/02/15**

Registration timing: **registered_while_recruiting**

Last update: **2020-05-04, 1399/02/15**

Update count: **0**

Registration date

2020-05-04, 1399/02/15

Registrant information

Name

Gholamreza Askari

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 1792 2110

Email address

askari@mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-04, 1399/02/15

Expected recruitment end date

2020-06-04, 1399/03/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of curcumin-piperine supplementation on disease duration, severity and clinical signs, and inflammatory factors in patients with coronavirus(COVID-19): A randomized, double-blind, placebo-controlled clinical trial study

Public title
Effect of curcumin-piperine in patients with coronavirus(COVID-19)

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Tendency to participate in the study People aged 18-65 years Diagnosis of Covid-19 based on clinical findings and imaging findings (Chest X Ray), CT scan or PCR
Exclusion criteria:
Age less than 20 and more than 75 years Taking warfarin Sensitivity to plant products such as turmeric and pepper

Age
From **20 years** old to **75 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomly, based on the permuted block randomization method, using blocks of 4 that will be blocked based on gender variables and will be assigned to one of two curcumin and placebo groups. The enrolling participants, and assigning participants to the groups will be carried out by a trained nutritionist. Researchers will not be informed about randomization process until completion of data analyses.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study is a double blind clinical trial (participant, researcher). The curcumin supplement and its placebo will be packaged in similar boxes, and the researcher and patients will not be informed of the contents of the packs until the end of the study.

Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Hezarjarib Ave., Isfahan University of Medical Sciences

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2020-04-18, 1399/01/30

Ethics committee reference number

IR.MUI.MED.REC.1399.049

Health conditions studied

1

Description of health condition studied

coronavirus (covid-19) disease

ICD-10 code

U07.02

ICD-10 code description

COVID-19 Disease

Primary outcomes

1

Description

CT of the chest

Timepoint

Before intervention and 2 weeks after intervention

Method of measurement

Find out - Photos - CT

2

Description

Body temperature

Timepoint

Before intervention and 2 weeks after intervention

Method of measurement

By using clinical thermometer

3

Description

Duration of hospitalization

Timepoint

At the time of discharge from the hospital

Method of measurement

By Using the patient's medical record

4

Description

hs-CRP

Timepoint

Before intervention and 2 weeks after intervention

Method of measurement

Enzymatic method

5

Description

ESR

Timepoint

Before intervention and 2 weeks after intervention

Method of measurement

Enzymatic method

6

Description

ALT

Timepoint

Before intervention and 2 weeks after intervention

Method of measurement

Enzymatic photometric method

7

Description

AST

Timepoint

Before intervention and 2 weeks after intervention

Method of measurement

Enzymatic photometric method

8

Description

LDH

Timepoint

Before intervention and 2 weeks after intervention

Method of measurement

Enzymatic photometric method

9

Description

BUN

Timepoint

Before intervention and 2 weeks after intervention

Method of measurement

urine sample

10

Description

creatinine

Timepoint

Before intervention and 2 weeks after intervention

Method of measurement

by laboratory kit

11

Description

CBC

Timepoint

Before intervention and 2 weeks after intervention

Method of measurement

blood sample

12

Description

blood oxidative stress indices (SOD, MDA, TAC)

Timepoint

Before intervention and 2 weeks after intervention

Method of measurement

By using available commercial kits

13

Description

Albumin

Timepoint

Before intervention and 2 weeks after intervention

Method of measurement

blood sample

14

Description

Severity of the disease

Timepoint

Before intervention and 2 weeks after intervention

Method of measurement

By using clinical and laboratory evaluations

15

Description

severity and number of coughs

Timepoint

Before intervention and 2 weeks after intervention

Method of measurement

Visual analogue scales (VAS) for cough

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Two curcumin-piperine capsules (500

mg of curcumin + 5 mg of piperine) will be given daily for 2 weeks after lunch and dinner.

Category

Treatment - Other

2

Description

Control group: 2 placebos (500 mg of maltodextrin) daily after lunch and dinner for 2 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Hospitals affiliated with Isfahan University of Medical Sciences

Full name of responsible person

Gholamreza Askari

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Ostandari Ave.

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askari@mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjou

Street address

Hezar Jarib Ave, Isfahan University of Medical Sciences

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81746-73461

Phone

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sh_haghjoo@med.mui.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Gholamreza Askari

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Gholamreza Askari

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Gholamreza Askari

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Nutrition

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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

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

The collected deidentified for the primary outcome measure only will be shared.

When the data will become available and for how long

12 months after publication

To whom data/document is available

Available for people working in academic institutions

Under which criteria data/document could be used

To conduct similar studies

From where data/document is obtainable

askari@mui.ac.ir

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

The data will send as soon as possible, after receiving the request.

Comments