

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Mar 2023

Evaluation the anti-inflammatory effects of curcumin in the treatment of patients with COVID-19

Protocol summary

Study aim

Evaluation of anti-inflammatory effect of curcumin in the treatment of patients with COVID-19

Design

a non-randomized open label, parallel group clinical trial on 60 patients With covid-19 (30 patients in the treatment group and 30 patients in the control group)

Settings and conduct

60 COVID-19 infected patients in Razi Hospital, Ahvaz, at the same time as receiving the national treatment protocol for CoVID-19 treatment, are categorized in two groups receiving nano-curcumin capsules (three 80 mg capsules per day) for one week and control. Before and after the intervention (days 0 and 7), blood samples were collected from patients in both groups and the gene expression of TNF-a, IL-1, IL-6 and IFN-G inflammatory cytokines assesed using real-time RT-PCR as well as serum concentrations of inflammatory cytokines TNF-a, IL-1 and IL-6 are measured using ELISA technique. Also, demographic characteristics, clinical symptoms and laboratory findings of patients are collected through checklists.

Participants/Inclusion and exclusion criteria

1- Confirmed COVID-19 infection 2- Conscious consent to participate in the study

Intervention groups

- Treatment group: Three nno-curcumin capsules 80 mg three times a day for 1 week (7 days) - Control group: no intervention

Main outcome variables

cytokines gene expression, cytokines serum levels, clinical symptoms, laboratory findings

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200519047510N1**

Registration date: **2020-05-28, 1399/03/08**

Registration timing: **prospective**

Last update: **2020-05-28, 1399/03/08**

Update count: **0**

Registration date

2020-05-28, 1399/03/08

Registrant information

Name

Ali Asadirad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3332 2316

Email address

ali.asadirad@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-05, 1399/03/16

Expected recruitment end date

2020-06-21, 1399/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the anti-inflammatory effects of curcumin in the treatment of patients with COVID-19

Public title

Evaluation the anti-inflammatory effects of curcumin in the treatment of patients with COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Confirmed COVID-19 infection
Conscious consent to participate in the study

Exclusion criteria:

Pregnancy and lactation
Long-term use of immunosuppressive drugs
Use of nutritional supplements
Dissatisfaction to participate in the study

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 Ahvaz Jundishapur University of Medical Sciences

Street address

Esfand Ave., Golestan

City

Ahvaz

Province

Khuzestan

Postal code

6135715794

Approval date

2020-05-17, 1399/02/28

Ethics committee reference number

IR.AJUMS.REC.1399.176

Health conditions studied

1

Description of health condition studied

COVID-19

ICD-10 code

U07.1

ICD-10 code description

Corona virus infection, unspecified

Primary outcomes

1

Description

Gene expression of inflammatory cytokines in peripheral blood mono-nuclear cells of patients receiving nanocurcumin and the control group

Timepoint

Before and after the intervention (0 and 7 days)

Method of measurement

real time-PCR

2

Description

Serum levels of inflammatory cytokines of patients receiving nanocurcumin and the control group

Timepoint

Before and after the intervention (0 and 7 days)

Method of measurement

ELISA technique

3

Description

Clinical symptoms of patients receiving nanocurcumin and the control group

Timepoint

Before and after the intervention (0 and 7 days)

Method of measurement

Examination by a specialist

4

Description

Laboratory findings of patients receiving nanocurcumin and the control group

Timepoint

Before and after the intervention (0 and 7 days)

Method of measurement

Laboratory findings in the Patient file

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: receiving 3 nanocurcumin 80 mg capsules (240 mg) for 7 days at the same time with

common therapeutic protocol

Category

Treatment - Drugs

2

Description

Control group: received common therapeutic protocols and not nanocurcumin

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Hospital, Ahvaz

Full name of responsible person

Roohangiz Nashibi

Street address

No. 35, Western 7 Ave., Kian Abad

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6155716348

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+98 61 3391 9395

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roohangizenashibi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mohammad Badavi

Street address

Main building, Ahvaz University of Medical Science, Golestan

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6135539345

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Badavi-m@ajums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Ali Asadirad

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Immunology

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Person responsible for scientific inquiries

Contact

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Position

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Latest degree

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Person responsible for updating data

Contact

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Ahvaz University of Medical Sciences
Full name of responsible person
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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