

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

20 Oct 2020

### 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

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

6155716348

**Phone**

+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

**City**

Ahvaz

**Province**

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**Postal code**

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**Phone**

+98 61 3311 3815

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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 updating data

### Contact

**Name of organization / entity**  
Ahvaz University of Medical Sciences  
**Full name of responsible person**  
Ali Asadirad  
**Position**  
Assistant professor  
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Immunology  
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**Province**  
Khouzestan  
**Postal code**

## 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