

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

25 Jun 2026

### Evaluation of the effect of quercetin on the effectiveness of antiviral drug regimen in patients with COVID19

#### Protocol summary

##### Study aim

Evaluation of the effect of Quercetin on the effectiveness of antiviral drug regimen in patients with COVID19

##### Design

This study is a two arm parallel groups clinical trial that will be done in Ahvaz hospital. Randomization is done through block method. Sample size of this study is 60 patients that divided equally into two groups include intervention and control group . Intervention and control groups treat with the same method, except the intervention group that receive 2 Tabs Quercetin from Jarrow Formulas. This a phase 3 clinical trial. In both groups clinical outcome and side effects are evaluated.

##### Settings and conduct

A randomized clinical trial that will be done in Ahvaz hospital. According to inclusion and exclusion criteria, patients are randomly divided into 2 groups. Both groups receive the same treatment. Intervention group will receive 2 Tabs Quercetin from Jarrow Formulas daily until 7 days. Blinding is not done in our study.

##### Participants/Inclusion and exclusion criteria

Polymerase chain reaction (PCR) confirmed infection with COVID19 Lung involvement confirmed with chest imaging Hospitalized with Or Cough Willingness of study participant to accept randomization to any assigned treatment arm Acceptance of non-participation in another study before the 28th day of the study

##### Intervention groups

Intervention group: 2 Tabs Quercetin from Jarrow Formulas, daily until 7days. Both case and control group will be received routine drugs.

##### Main outcome variables

Time to clinical recovery, respiratory signs, Intubation rate.

#### General information

##### Reason for update

In order to more accurately record clinical trial

information, some changes in the study Design, Inclusion and exclusion criteria have been updated. The ICD-10 code description was revised

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200419047128N2**

Registration date: **2020-04-24, 1399/02/05**

Registration timing: **prospective**

Last update: **2021-07-04, 1400/04/13**

Update count: **1**

##### Registration date

2020-04-24, 1399/02/05

##### Registrant information

##### Name

Ali Khodadadi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 3331 1061

##### Email address

akhodadadi2@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-04-29, 1399/02/10

##### Expected recruitment end date

2020-05-09, 1399/02/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of the effect of quercetin on the effectiveness of antiviral drug regimen in patients with COVID19

## Public title

Quercetin in COVID19

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Polymerase chain reaction (PCR) confirmed infection with COVID19 Lung involvement confirmed with chest imaging Hospitalized with: Fever (axillar or oral temperature  $\geq 38.0$  °centigrade(C) or  $\geq 38.6$ °centigrade tympanic or rectal) Or Cough Willingness of study participant to accept randomization to any assigned treatment arm Acceptance of non-participation in another study before the 28th day of the study

### Exclusion criteria:

Autoimmune diseases (lupus, MS, etc.) Hepatic failure Hepatit B, C, pregnant and lactating women Not consent to participate in the study

## Age

No age limit

## Gender

Both

## Phase

3

## Groups that have been masked

No information

## Sample size

Target sample size: 60

## Randomization (investigator's opinion)

Randomized

## Randomization description

Patients are divided into two Therapeutic groups by random method and used 6 blocks method. Individuals are the randomization unit , making a random sequence is by using statistical software(WinPepi11.0). Allocation concealment is by assigning unique codes

## 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 University of medical

##### Street address

Golestan

##### City

Ahvaz

## Province

Khuzestan

## Postal code

15794-61357

## Approval date

2020-04-18, 1399/01/30

## Ethics committee reference number

IR.AJUMS.REC.1399.087

## Health conditions studied

### 1

#### Description of health condition studied

COVID19

#### ICD-10 code

U07.1

#### ICD-10 code description

Corona virus infection, unspecified

## Primary outcomes

### 1

#### Description

Viral diagnostic test

#### Timepoint

The first day of the study and the end of the study (14th)

#### Method of measurement

Polymerase chain reaction

## Secondary outcomes

### 1

#### Description

Blood oxygen saturation percentage

#### Timepoint

Before and 4-7 days after starting treatment

#### Method of measurement

Pulse oximeter

### 2

#### Description

Cough rate

#### Timepoint

Before and 7 days after starting treatment

#### Method of measurement

Physical examination

### 3

#### Description

C-Reactive Protein (CRP)

#### Timepoint

Before and 7 days after starting treatment

#### Method of measurement

ELISA (enzyme-linked immunosorbent assay)

#### 4

##### **Description**

IL1

##### **Timepoint**

Before and 7 days after starting treatment

##### **Method of measurement**

ELISA (enzyme-linked immunosorbent assay)

#### 5

##### **Description**

IL6

##### **Timepoint**

Before and 7 days after starting treatment

##### **Method of measurement**

ELISA (enzyme-linked immunosorbent assay)

#### 6

##### **Description**

CBC

##### **Timepoint**

Before and 7 days after starting treatment

##### **Method of measurement**

Cell Counter

### **Intervention groups**

#### 1

##### **Description**

Intervention group: 2 Tabs Quercetin(500mg) from Jarrow Formulas , daily until 7 days. Both case and control group will be received routine drugs.

##### **Category**

Treatment - Drugs

#### 2

##### **Description**

Control group: this group doesn't receive extra drugs. Both groups receive routine drugs.

##### **Category**

Treatment - Drugs

### **Recruitment centers**

#### 1

##### **Recruitment center**

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

Razi hospital

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

Ali Khodadadi

###### **Street address**

Razi hospital, Felestin Ave, Amanieh Ave

###### **City**

Khuzestan

###### **Province**

Khuzestan

###### **Postal code**

6155819953

##### **Phone**

+98 61 3555 0592

##### **Email**

akhodadadi2@gmail.com

### **Sponsors / Funding sources**

#### 1

##### **Sponsor**

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

Ahvaz University of Medical Sciences

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

Mohamad Badavi

###### **Street address**

Main building, Ahvaz University of Medical Science, Golestan

###### **City**

Ahvaz

###### **Province**

Khuzestan

###### **Postal code**

6135539345

###### **Phone**

+98 61 3311 3815

###### **Email**

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 khodadadi

###### **Position**

Associate Professor

###### **Latest degree**

Ph.D.

###### **Other areas of specialty/work**

Immunology

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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)

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