

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation of the effect of Resveratrol on the effectiveness of antiviral drug regimen in patients with COVID-19

#### Protocol summary

##### Study aim

Assessment The effect of resveratrol supplementation on some inflammatory factors in patients with severe 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 groups .This is a phase 3 clinical trial.

##### Settings and conduct

This study is a two arm parallel groups clinical trial that will be done in Ahvaz hospital. In this study, blindness is not performed.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 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 respiratory rate  $>24$ /min or cough; Less than 8 days since illness. Non-inclusion criteria: Autoimmune diseases (lupus, MS, etc.); Hepatic failure; Hepatit B, C; pregnant and lactating women

##### Intervention groups

Both case and control group will be received routine drugs. 1. Intervention group: Resveratrol produced by Sumabe company, one Tab, daily until 14 days. 2. control group: received routine drugs.

##### Main outcome variables

Time to clinical recovery, respiratory signs, Intubation rate.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200112046089N1**

Registration date: **2020-06-25, 1399/04/05**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-06-25, 1399/04/05**

Update count: **0**

##### Registration date

2020-06-25, 1399/04/05

##### Registrant information

###### Name

Arash Alghasi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 61 3374 3289

###### Email address

arashalqasi@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-06-14, 1399/03/25

##### Expected recruitment end date

2020-07-15, 1399/04/25

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of the effect of Resveratrol on the effectiveness of antiviral drug regimen in patients with COVID-19

##### Public title

Resveratrol in COVID19

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Polymerase chain reaction (PCR) confirmed infection with SARS CoV2 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 Respiratory rate  $>24$ /min Or Cough Less than 8 days since illness onset Willingness of study participant to accept random assignment to any 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 and C pregnant and lactating women

## Age

No age limit

## Gender

Both

## Phase

3

## Groups that have been masked

No information

## Sample size

Target sample size: 50

## Randomization (investigator's opinion)

Randomized

## Randomization description

Patients are divided into two therapeutic groups by block randomization method using blocks of size 6. 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 Sciences

##### Street address

Golestan highway

##### City

Ahvaz

##### Province

Khuzestan

## Postal code

15794-61357

## Approval date

2020-05-16, 1399/02/27

## Ethics committee reference number

IR.AJUMS.REC.1399.175

## Health conditions studied

### 1

#### Description of health condition studied

COVID19

#### ICD-10 code

U07.1

#### ICD-10 code description

COVID-19, virus identified

## Primary outcomes

### 1

#### Description

Recovery time

#### Timepoint

Duration of treatment

#### Method of measurement

Evaluation of clinical symptoms

### 2

#### Description

Repiratory signs

#### Timepoint

daily

#### Method of measurement

clinical evaluation and questionnaire

### 3

#### Description

Pulmonary Condition

#### Timepoint

Before intervention and 14 days after intervention

#### Method of measurement

CT scan

## Secondary outcomes

### 1

#### Description

Blood oxygen saturation percentage

#### Timepoint

Before and 14 days after starting treatment

#### Method of measurement

Pulse oximeter

### 2

#### Description

C-Reactive Protein (CRP)

### **Timepoint**

Before and fourteen days after starting treatment

### **Method of measurement**

ELISA (enzyme-linked immunosorbent assay)

### **3**

#### **Description**

IL6

#### **Timepoint**

Before and 14 days after starting treatment

#### **Method of measurement**

ELISA (enzyme-linked immunosorbent assay)

### **4**

#### **Description**

IL1

#### **Timepoint**

Before and 14 days after starting treatment

#### **Method of measurement**

ELISA (enzyme-linked immunosorbent assay)

### **5**

#### **Description**

CBC

#### **Timepoint**

Before and 14 days after starting treatment

#### **Method of measurement**

Cell Counter

## **Intervention groups**

### **1**

#### **Description**

Intervention group: 1 Tab resveratrol (500mg) from Sumabe, daily until 14 days in addition to routine drugs.

#### **Category**

Treatment - Drugs

### **2**

#### **Description**

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

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### **1**

#### **Recruitment center**

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

Razi hospital

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

Arash Alghasi

##### **Street address**

Razi hospital, Felestin boulevard, Amanieh

##### **City**

Ahvaz

##### **Province**

Khouzestan

##### **Postal code**

6155819953

##### **Phone**

+98 61 3555 0592

##### **Email**

arashalqasi@yahoo.com

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

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

Ahvaz University of Medical Sciences

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

Mohamad Badavi

##### **Street address**

Vice Chancellor of Research and Technology; Main building of Ahvaz University of Medical Science, Golestan highway

##### **City**

Ahvaz

##### **Province**

Khouzestan

##### **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**

Arash Alghasi

##### **Position**

Assistant Professor of Pediatric Hematology and Oncology

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Pediatric Hematology and Oncology

**Street address**

Ahvaz Shahid Baghaei 2 hospital; Golestan highway

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

6135539345

**Phone**

+98 61 3374 3289

**Email**

alghasi-a@ajums.ac.ir

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Mohammad Reza Mahmoudian-Sani

**Position**

Assistant Professor of Molecular Medicine School of Medicine

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Molecular Medicine

**Street address**

Ahvaz Shahid Baghaei 2 hospital; Golestan highway

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

6135539345

**Phone**

+98 61 3374 3289

**Email**

mohamadsani495@gmail.com

**Person responsible for updating data****Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Arash Alghasi

**Position**

Assistant Professor of Pediatric Hematology and Oncology Department of Pediatrics, School of Medicine

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Pediatric Hematology and Oncology

**Street address**

Ahvaz Shahid Baghaei 2 hospital; Golestan highway

**City**

Ahvaz

**Province**

Khuzestan

**Postal code**

6135539345

**Phone**

+98 61 3374 3289

**Email**

alghasi-a@ajums.ac.ir

**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