

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jun 2026

### Evaluation of the effects of resveratrol consumption on inflammatory and biochemical parameters of patients with Covid 19

#### Protocol summary

##### Study aim

Evaluation of the effect of resveratrol consumption on inflammatory and biochemical factors in patients with Covid 19

##### Design

This study is a randomized, double-blinded, controlled clinical trial with a parallel group design of 140 patients (70 patients in each group). The random allocation method in this study will be per mutated block randomization.

##### Settings and conduct

The patients with Covid-19 will be going to Persian Gulf Hospital, Bushehr, Iran, to do the PCR test and the assessment of their conditions for entering the trial. After completing the consent and questionnaire forms, the patients will receive the resveratrol and placebo packages which are labeled based on computer-generated codes. Each of these codes is determined based on the sequence of random allocation of individuals to groups. Then, blood collection will take place at this time and after the 10 days of intervention. The project manager, the only person who is aware of the codes and the order in which individuals are assigned to groups, is not involved in any of the evaluation and measurement of outcomes steps. The patient and the outcome evaluator will not know the type of intervention.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age above 18 years. Having Covid -19, Lung involvement approved by CT scan. Exclusion criteria: Pregnant ladies The patients with any allergic or sensitivity,

##### Intervention groups

The patients in the intervention group will receive 250 mg resveratrol capsules (99% pure, Biotivia, Bioceuticals International Sri, Italy), 3 times a day for 10 days. The patients in the placebo group will receive 250 mg of placebo capsules (totally inert nitrocellulose, Biotivia, Bioceuticals International Sri, Italy) supplementation 3 times a day for 10 days.

#### Main outcome variables

Lung involvement, ESR; CBC index; CRP

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20111119008129N13**

Registration date: **2022-10-11, 1401/07/19**

Registration timing: **prospective**

Last update: **2022-10-11, 1401/07/19**

Update count: **0**

##### Registration date

2022-10-11, 1401/07/19

##### Registrant information

##### Name

Ali Movahed

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 77 3332 4044

##### Email address

a.movahed@bpums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-10-17, 1401/07/25

##### Expected recruitment end date

2022-11-16, 1401/08/25

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Evaluation of the effects of resveratrol consumption on inflammatory and biochemical parameters of patients with Covid 19

**Public title**

Evaluation of the effects of resveratrol in patients with Covid 19

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

Female and Male with the age between 18 to 55 years  
Long involvement approved by city scan Admitted to the hospital with Fever(  $\geq 38\text{ C}^\circ$ ) The breath rate  $\geq 24/\text{min}$ , or coughing ( before the 8th day of the disease )  
Infection with covid 19, approved by PCR

**Exclusion criteria:**

Pregnant women Patients with kidney Disease, Patients with hypercalcemia and hypercalciuria Patients with any type of allergic diseases Having any kind of disease by which the patients can't have a proper participation  
Inability to behave properly( having Mental problem Auto immune diseases ( having MS, Lupus ...) Kidney Failure, Hepatitis B and C Patients with acute covid 19 symptoms

**Age**

From **18 years** old to **55 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Data analyser

**Sample size**

Target sample size: **140**

More than 1 sample in each individual

Number of samples in each individual: **2**

After the completion of the questionnaire,the samples will be collected before the intervention starts and after 10 days of resveratreol consumption or placebo.

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The random allocation method in this study will be permuted block randomization, where T represents the person receiving the intervention and C represents the person who receive the Placebo. This method is performed by considering blocks of sizes 4 patients so that the total number of 4 permutations is equal to 6 blocks as follows: (C,C,T,T), (T,T,C,C), (C,T,T,C), (C,T,C,T), (T,C,C,T), (T,C,T,C), (C,T,C,T) Then, a number of 35 blocks will be randomly selected with replacement from these 6 blocks. Finally, the desired list of 35 blocks of 4 ( $4 * 35 = 140$  total number of samples) is generated and the order of assignment to each of the samples participating in the study is determined. These steps are performed using R

software version 3.6.3

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

First, all resveratrol and placebo capsules are prepared in the same shape and size and in packs of 20 for distribution to patients. The resveratrol and placebo packages are then labeled based on computer-generated codes (without indication of its content). Each of these codes is determined based on the sequence of random allocation of individuals to groups. The project manager, the only person who is aware of the codes and the order in which individuals are assigned to groups, is not involved in any of the evaluation and measurement of outcomes steps. On the other hand, the shape, size, and type of packaging of the resveratrol and placebo are exactly the same, so the patient and the outcome evaluator will not know the type of intervention.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Bushehr University of Medical Sciences,Office of deputy adviser for research

**Street address**

Pardis Site, Next to Salmon Farsi Hospital, Department of Research,Bushehr University of Medical Science Bushehr Bushehr Iran, Islamic Republic Of 751473537

**City**

Bushehr

**Province**

Boushehr

**Postal code**

98751473537

**Approval date**

2021-11-14, 1400/08/23

**Ethics committee reference number**

IR.BPUMS.REC,1400,159

**Health conditions studied****1****Description of health condition studied**

Covid-19

**ICD-10 code**

U07

**ICD-10 code description**

COVID-19, virus identified

## Primary outcomes

### 1

#### **Description**

Pulmonary involvement

#### **Timepoint**

The time of measurement will be after interventions for a period of 10 days, for all the participants in both groups.

#### **Method of measurement**

Results of CT scan (chest radiography)

## Secondary outcomes

### 1

#### **Description**

CBC Test

#### **Timepoint**

The time of measurement will be after interventions for a period of 10 days, for all the participants in both groups.

#### **Method of measurement**

By blood Auto-analyzer

### 2

#### **Description**

Erythrocyte sedimentation rate (ESR)

#### **Timepoint**

The time of measurement will be after interventions for a period of 10 days, for all the participants in both groups.

#### **Method of measurement**

By ESR Reader

### 3

#### **Description**

CRP

#### **Timepoint**

The time of measurement will be after interventions for a period of 10 days, for all the participants in both groups.

#### **Method of measurement**

By biochemistry auto analyzer- spectrophotometer

### 4

#### **Description**

Interleukin-1

#### **Timepoint**

The time of measurement will be after interventions for a period of 10 days, for all the participants in both groups.

#### **Method of measurement**

By ELISA

### 5

#### **Description**

Interleukin-6

#### **Timepoint**

The time of measurement will be after interventions for a period of 10 days, for all the participants in both groups.

#### **Method of measurement**

By ELISA

### 6

#### **Description**

TNF $\alpha$

#### **Timepoint**

The time of measurement will be after interventions for a period of 10 days, for all the participants in both groups.

#### **Method of measurement**

By ELISA

### 7

#### **Description**

Alanine amino transferase

#### **Timepoint**

The time of measurement will be after interventions for a period of 10 days, for all the participants in both groups.

#### **Method of measurement**

By biochemistry auto analyzer- spectrophotometer

### 8

#### **Description**

Aspartate Aminotransferase (AST)

#### **Timepoint**

The time of measurement will be after interventions for a period of 10 days, for all the participants in both groups.

#### **Method of measurement**

By biochemistry auto analyzer- spectrophotometer

### 9

#### **Description**

Alkaline Phosphatase (ALP)

#### **Timepoint**

The time of measurement will be after interventions for a period of 10 days, for all the participants in both groups.

#### **Method of measurement**

By biochemistry auto analyzer- spectrophotometer

### 10

#### **Description**

FBS

#### **Timepoint**

The time of measurement will be after interventions for a period of 10 days, for all the participants in both groups.

#### **Method of measurement**

By biochemistry auto analyzer- spectrophotometer

### 11

#### **Description**

BMI

#### **Timepoint**

The time of measurement will be after interventions for a period of 10 days, for all the participants in both groups.

#### **Method of measurement**

Scales and meters

### 12

#### **Description**

BUN

### Timepoint

The time of measurement will be after interventions for a period of 10 days, for all the participants in both groups.

### Method of measurement

By biochemistry auto analyzer- spectrophotometer

## 13

### Description

Creatinine

### Timepoint

The time of measurement will be after interventions for a period of 10 days, for all the participants in both groups.

### Method of measurement

By biochemistry auto analyzer- spectrophotometer

## Intervention groups

### 1

### Description

Intervention group: The patients will take resveratrol capsules(99% pure, Biotivia, Bioceuticals International Srl, and Italy, 250 mg, 3 times /day, in the morning, afternoon, and at night for a period of 7 days.

### Category

Prevention

### 2

### Description

Control group: The patients will take neutral micro-cellulose capsules, Biotivia, Bioceuticals International Srl, and Italy, 250 mg, 3 times /day, in the morning, afternoon, and at night for a period of 7 days.

### Category

Placebo

## Recruitment centers

### 1

### Recruitment center

#### Name of recruitment center

The medical Laboratory of persian gulf shohada Hospital, Bushehr, Iran

#### Full name of responsible person

Ali Movahed,

#### Street address

Moallem ST, Bushehr University of Medical Sciences,

#### City

Bushehr

#### Province

Boushehr

#### Postal code

987514633341

#### Phone

+98 77 3332 4044

#### Email

amovahed58@gmail.com

## Sponsors / Funding sources

### 1

### Sponsor

#### Name of organization / entity

Boushehr University of Medical Sciences

#### Full name of responsible person

Akram Farhadi

#### Street address

Bushehr University of Medical Sciences, Department of Resaerch, Salmon Farsi Street, Bahmani, Bushehr, Iran

#### City

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#### Province

Boushehr

#### Postal code

987518759577

#### Phone

+98 77 4533 0178

#### Email

Research@BPUMS.ac.ir

### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

Boushehr 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

Boushehr University of Medical Sciences

#### Full name of responsible person

Ali Movahed

#### Position

Academic Member,

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Biochemistry

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Boushehr University of Medical Sciences

**Full name of responsible person**

Ali Movahed

**Position**

Academic Member

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Biochemistry

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## Person responsible for updating data

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**Position**

Academic Member

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Ph.D.

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is 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**

Yes - There is a plan to make this available

**Title and more details about the data/document**

The Deputy of Research is responsible to provide the information and documents to the participants in the Trial

**When the data will become available and for how long**

After the trial was over and the results were analyzed, for a period of one year, access to the document is possible

**To whom data/document is available**

The data and other documents of the study will be given to my colleagues at my University and other researchers and academic members from different universities worldwide.

**Under which criteria data/document could be used**

If the researcher wants the document to use in the following research. The patients who want to know about the results of the examination

**From where data/document is obtainable**

The main investigator responsible for the trial, or the deputy of Research should be contacted

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

The applicants should submit a request letter to the principal investigator, or a request from the deputy of research. Then, the request will be assessed by these authorities and the right files and documents will be submitted to the requester for a period of one or two weeks.

**Comments**