

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### Evaluation of levamisole on treatment of patients with COVID 19 infection: a controlled clinical trial study.

#### Protocol summary

##### Study aim

Evaluation of the effect of Levamisole on treatment of the patients with COVID-19 infection

##### Design

In this study every patient with diagnosis of COVID-19 and with sign and symptoms will be selected and will be randomized in control and interventional groups. 20 patients will be selected with mild, moderate and severe condition (overall 60) and in every condition group 10 patients, will be randomized with block randomization method in control and interventional groups.

##### Settings and conduct

After randomization, in interventional group levamisole 50 mg daily for 14 days will be administered in addition to standard therapy and in control group only standard therapy will be administered.

##### Participants/Inclusion and exclusion criteria

the patients with COVID 19 infection

##### Intervention groups

In this study the selected patients will be set into two groups. In interventional group levamisole will be administered and in the control group any drug will be given,

##### Main outcome variables

clinical status, Blood O2 saturation, Hemodynamic state

#### General information

##### Reason for update

##### Acronym

لواميزول

##### IRCT registration information

IRCT registration number: **IRCT20181208041886N1**

Registration date: **2020-10-18, 1399/07/27**

Registration timing: **prospective**

Last update: **2020-10-18, 1399/07/27**

Update count: **0**

##### Registration date

2020-10-18, 1399/07/27

##### Registrant information

###### Name

Morteza Pourahmad

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 3322 0197

###### Email address

mortezapourahmad@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-10-22, 1399/08/01

##### Expected recruitment end date

2021-03-17, 1399/12/27

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of levamisole on treatment of patients with COVID 19 infection: a controlled clinical trial study.

##### Public title

Levamisole in treatment of COVID19.

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

###### Inclusion criteria:

age  $\geq$  or  $>$  18 years Diagnosis of COVID19 infection was made by positive test for RtPCR on nasopharyngeal swab, Lung HRCT and the opinion of infectious diseases

specialist. informed consent of patient for study the possibility of patient follow up.

**Exclusion criteria:**

Another cause for signs and symptoms hypersensitivity to levamisole consumption of other antibiotics on the neck. Dyspnea Pregnancy breast feeding

**Age**

From **18 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

The selected patients on inclusion and exclusion criteria will be randomized in two experimental and control groups in 15 randomized block. In every block 4 patients will be setelled (2 patient as control and 2 as interventional). At first the physician will visit the patients and on the clinical criteria he/she decided that the disease is mild, moderate and / or sever and the patient will setelled in the blocks and groups (control or interventional).

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In this study the patients and the physician who evaluate the signs and symptoms of the patients are blinded about the therapy. To prevent of the bias the levamisole tablet will be give the patients accompanied with other drugs. On the other hand the assessor also will not be informed about the drugs of the patients.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

nothing

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Ethics committee of Isfahan University of Medical Sciences

**Street address**

Sofeh Street

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8189111491

**Approval date**

2020-06-22, 1399/04/02

**Ethics committee reference number**

IR.MUI.MED.REC.1399.246

**Health conditions studied**

**1**

**Description of health condition studied**

COVID19

**ICD-10 code**

U07.1

**ICD-10 code description**

U07.1 COVID-19, virus identified•U07.2 COVID-19, virus not identifiedoClinically-epidemiologically diagnosed COVID-19oProbable COVID-19 oSuspected COVID-19

**Primary outcomes**

**1**

**Description**

Discontinuation of fever

**Timepoint**

Daily

**Method of measurement**

evaluation by a physician

**2**

**Description**

improvement of dyspnea

**Timepoint**

Daily

**Method of measurement**

evaluation by physician

**3**

**Description**

decreasing of cough

**Timepoint**

Daily

**Method of measurement**

evaluation by physician

**4**

**Description**

elevation of O2sat of the blood

**Timepoint**

Daily

**Method of measurement**

evaluation by physician

## 5

### **Description**

blood pressure improvement

### **Timepoint**

Daily

### **Method of measurement**

evaluation by physician

## 6

### **Description**

pulse rate improvement

### **Timepoint**

Daily

### **Method of measurement**

evaluation by physician

## **Secondary outcomes**

## 1

### **Description**

improvement of the patient which has had COVID-19>

### **Timepoint**

14 days

### **Method of measurement**

evaluation of the patient by a physician

## **Intervention groups**

## 1

### **Description**

Intervention group: the patients with diagnosis of COVID19 with be treated by tablet Levamisole 50 mg daily for 14 days in addition to standard therapies for these patients. the sign and symptoms of the patients will be evaluated daily.

### **Category**

Treatment - Drugs

## 2

### **Description**

Control group: the patient with diagnosis of COVID19 will give the standard therapies and without Levamisole.

### **Category**

Treatment - Drugs

## **Recruitment centers**

## 1

### **Recruitment center**

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

Al-Zahra Hospital

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

Morteza Pourahmad

#### **Street address**

Sofeh street

#### **City**

Isfahan

#### **Province**

Isfahan

#### **Postal code**

8189111491

#### **Phone**

+98 31 3322 0996

#### **Fax**

#### **Email**

mortezapourhamad@yahoo.com

## **Sponsors / Funding sources**

## 1

### **Sponsor**

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

Esfahan University of Medical Sciences

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

Dr. Shaghayegh Haghjoo, Research assistant of Isfahan University of Medical Sciences

#### **Street address**

Hezar Jerib street

#### **City**

Isfahan

#### **Province**

Isfahan

#### **Postal code**

8189111491

#### **Phone**

+98 31 3792 3078

#### **Email**

shaghayegh.haghjoo@gmail.com

### **Grant name**

### **Grant code / Reference number**

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

No

### **Title of funding source**

Research assistant of Isfahan 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**

Esfahan University of Medical Sciences

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

Morteza Pourahmad

#### **Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Infectious diseases

**Street address**

Sofeh street

**City**

Isfahan

**Province**

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**Postal code**

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**Phone**

+98 31 3322 0996

**Email**

mortezapourahmad@yahoo.com

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

Esfahan University of Medical Sciences

**Full name of responsible person**

Morteza Pourahmad

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Infectious diseases

**Street address**

Sofe Street

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8189111491

**Phone**

+98 31 3322 0996

**Email**

mortezapourahmad@yahoo.com

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

Esfahan University of Medical Sciences

**Full name of responsible person**

Morteza Pourahmaed

**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**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is 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 article from this study will be distributed the effect of Levamisole on treatment of COVID 19 infection

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

immediately after article publish

**To whom data/document is available**

Every body

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

no condition

**From where data/document is obtainable**

published article

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

No procedure

**Comments**

No comment