# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 2026

## Evaluation of Levamisole efficacy and safety in combination with routine therapy in patients with Covid-19: a clinical trial

### Protocol summary

**Study aim**
Evaluation of Levamisole efficacy and safety in combination with routine therapy in patients with Covid-19 in a clinical trial

**Design**
At the beginning of the study, patients will be randomly divided into one of two groups by the permissive block method (25 patients each). The trial is in phase two.

**Settings and conduct**
This is a prospective, double-blind, randomized controlled clinical trial, and all of the above steps will be covered by the patient, physician,first performer, statistical consultant and evaluator.

**Participants/Inclusion and exclusion criteria**
Entry: Ages 18 to 60 years, Diagnosis of Covid-19 over the past 24 hours, No underlying disease Exclusion: Hospitalized patients, Patients currently taking levamisole for other uses such as parasitic infection, Ages less than 2 and over, Pregnancy and lactation, Patients with underlying diseases such as diabetes and hypertension

**Intervention groups**
Routine treatment includes hydroxychloroquine 200 mg twice daily for 5 days with acetaminophen 500 mg used during fever and diphenhydramine syrup 10 cc every 8 hours to control cough. Patients in the levamisole group receive 50 mg tablets orally three times daily for three days along with routine treatment. Patients in the control group will receive routine treatment and placebo.

**Main outcome variables**
clinical symptoms including fever, cough, shortness of breath in COVID-19 patients; need for hospitalization; mortality; Side effects that occur during treatment or severe side effects that lead to discontinuation of treatment.

### General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20190810044500N7**
Registration date: **2020-09-19, 1399/06/29**
Registration timing: **registered_while_recruiting**

Last update: **2020-09-19, 1399/06/29**
Update count: **0**

**Registration date**
2020-09-19, 1399/06/29

**Registrant information**
**Name**
Fatemeh Saghafi
**Name of organization / entity**
**Country**
Iran (Islamic Republic of)
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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2020-04-08, 1399/01/20

**Expected recruitment end date**
2021-02-08, 1399/11/20

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
Evaluation of Levamisole efficacy and safety in combination with routine therapy in patients with Covid-19: a clinical trial

**Public title**
Evaluation of Levamisole efficacy in treatment of Covid-19

**Purpose**
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Ages 18 to 60 years Diagnosis of Covid-19 over the past 24 hours Female patients are not exposed to pregnancy and do not become pregnant until thirty days later. Not taking levamisole for the past five days (due to 16-hour drug half-life) Patients suspected to covid-19 based on clinical signs and symptoms of CT scan and candidate for outpatient treatment No medication other than protocol No underlying disease

**Exclusion criteria:**
Hospitalized Patients Patients with hemodynamic instability History of cirrhosis, hepatitis and severe liver disease, severe renal failure (less than 30ml / min) Patients currently taking levamisole for other uses such as parasitic infection Patients with a history of allergic reaction or sensitivity to levamisole Patients receiving chemotherapy for cancer Pregnancy and lactation Ages less than 18 years and over 60 years Patients with underlying diseases including diabetes and hypertension

**Age**
From **18 years** old to **60 years** old

**Gender**
Both

**Phase**
2

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Data analyser

**Sample size**
Target sample size: **50**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
Patients will be randomly divided into two groups by the permissive block method(25 people per group)

**Blinding (investigator's opinion)**
Double blinded

**Blinding description**
All stages will be covered by the patient, physician,First performer, statistical consultant and evaluator. The first presenter identifies the sequence of assignment of patients according to the order of entry of the patients to the study and places the drugs in a uniform envelope for the patient's 5-day intake and identifies them with A or B codes. He then identifies the medications that are appropriate for each individual according to the above description and puts them in special envelopes and delivers them to patients.

**Placebo**
Used

**Assignment**
Parallel

**Other design features**
All patients who enter this study will complete and sign the consent form.A questionnaire is designed to provide information about the patient's condition, and all patients are asked all questions about entry and exit conditions, and on the basis of which consultation with a physician is decided on whether or not to enter the patient.After identifying and selecting the patients, they were given written consent (after being explained by the student about its content) and the eligible patients entered the baseline phase and then randomly entered into the study to receive one of the interventions.Patients included in the study will be selected from referrals to the Infectious Disease Clinic of Shahid Sadoughi Hospital in Yazd and will be randomly selected. Plasbo is prepared in the Pharmaceutical Laboratory of Shahid Sadoughi School of Pharmacy, Yazd

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Ethics Committee of Shahid Sadoughi University of Medical Sciences

**Street address**
yazd،shohaday gomnam blvd،shahid sadoughi university of medical sciences

**City**
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**Province**
Yazd

**Postal code**
8915173143

**Approval date**
2020-06-22, 1399/04/02

**Ethics committee reference number**
IR.SSU.REC.1399.063

## Health conditions studied

### 1

**Description of health condition studied**
COVID-19

**ICD-10 code**
B34.2

**ICD-10 code description**
Coronavirus infection, unspecified

## Primary outcomes

### 1

**Description**
clinical symptoms include fever, cough, shortness of breath

**Timepoint**
Before the intervention, after completion of the intervention
**Method of measurement**
Clinical examination

**2**

**Description**
Patients need to be hospitalized
**Timepoint**
Before the intervention, after completion of the intervention
**Method of measurement**
Clinical examination

## Secondary outcomes

**1**

**Description**
Mortality
**Timepoint**
after completion of the intervention
**Method of measurement**
Clinical examination

**2**

**Description**
Side effects that occur during treatment or severe side effects that lead to discontinuation of treatment.
**Timepoint**
Before the intervention, after completion of the intervention
**Method of measurement**
Clinical examination

## Intervention groups

**1**

**Description**
Control group: Routine treatment includes hydroxychloroquine 200 mg twice daily for 5 days with acetaminophen 4 mg used during fever and diphenhydramine syrup 10 cc every 8 hours to control cough.
**Category**
Placebo

**2**

**Description**
Intervention group: Patients in the levamisole group receive 50 mg tablets orally three times daily for three days along with routine treatment.
**Category**
Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Infectious Disease Clinic of Shahid Sadoughi Hospital of Yazd
**Full name of responsible person**
Amirreza Roustaei Firouzabad
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## Sponsors / Funding sources

**1**

**Sponsor**
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**Web page address**
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
No
**Title of funding source**
Yazd University of Medical Sciences
**Proportion provided by this source**
1
**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**
Yazd University of Medical Sciences
**Full name of responsible person**
Amirreza Roustaei Firouzabad
**Position**
University student
**Latest degree**
A Level or less
**Other areas of specialty/work**
Medical Pharmacy
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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