Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 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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+98 35 3820 3419

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f.saghafi@ssu.ac.ir

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
Yazd

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
Street address
Next to the main door of Shahid Sadoughi Hospital, Yazd, Safaiei, Hashem Baghaeipour Specialty Polyclinic
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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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