

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 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)

Phone

+98 35 3820 3419

Email address

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

City

Yazd

Province

Yazd

Postal code

8915857958

Phone

+98 35 3822 3828

Email

amirroustaei93@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Masoud Mirzaei

Street address

Bahonar Ave

City

Yazd

Province

Yazd

Postal code

8915173149

Phone

+98 35 3820 3419

Fax

+98 35 3820 3418

Email

mmirzaei@ssu.ac.ir

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

Street address

yazd- yazd-shohaday gomnam blvd-shahid sadoughi
university of medical sciences

City

Yazd

Province

Yazd

Postal code

8915173149

Phone

+98 35 3820 3419

Fax

+98 35 3820 3418

Email

amirroostaei93@gmail.com

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

Yazd University of Medical Sciences

Full name of responsible person

Fateme Saghafi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy

Street address

yazd- yazd-shohaday gomnam blvd-shahid sadoughi
university of medical sciences

City

Yazd

Province

Yazd

Postal code

8915173143

Phone

+98 35 3820 3419

Email

Saghfi.Fa@gmail.comhs

Person responsible for updating data**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

Street address

yazd- yazd-shohaday gomnam blvd-shahid sadoughi
university of medical sciences

City

Yazd

Province

Yazd

Postal code

8915173149

Phone

+98 35 3820 3419

Fax

+98 35 3820 3418

Email

amirroostaei93@gmail.com

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