Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of Levamisole efficacy in treatment of COVID-19 and comparing it to the common treatment: a Clinical Trial

Protocol summary

Study aim

Determining Levamisole efficacy in the treatment of outpatient COVID19 infected individuals

Design

Two arm-parallel-group randomized trial in phase 3 on a minimum of 250 patients.

Settings and conduct

It will be implemented in covid19 selected and referral-centers of Tehran and its districts. Patients with positive PCR for COVID19 are included in the study. over the first visit, patients are randomly assigned to control or case groups by the physician by the block randomization method. Patients are then followed up by health care providers 6 times. Due to the nature of levamisole, which is a tablet, the placebo can not be used in this study. In this study, blinding will not be possible(only the analyzer is blinded)

Participants/Inclusion and exclusion criteria

Inclusion criteria: 18 years or older Positive COVID-19 PCR ; Women should not become pregnant for 30 days after the end of the study patients should not take levamisole for five days before entering the study (because the half-life of the drug is 16 hours) Exclusion criteria: Bacterial or fungal infection; History of allergic reaction to levamisole; Use of drugs and antibiotics other than those used in the national COVID-19 treatment protocol; Shortness of breath due to cardiogenic pulmonary edema; Pregnancy Breastfeeding; Patients with unstable hemodynamics; History of cirrhosis, hepatitis, or severe liver disease, GFR less than 30 ml/min Patients receiving chemotherapy for cancer.

Intervention groups

In the control group, patients will receive the routine medicine prescribed based on the national protocol for the management of COVID19. In the intervention group, levamisole will be prescribed as an add-on therapy

Main outcome variables

The general condition of the patient; admission; mortality; Dyspnea; Cough; Diarrhea; Nausea; Vomiting; Myalgia; Headache; Fever; Anosmia; Dysgeusia

General information

Reason for update

in order to expedite collecting the sample size, we implemented the trial as a multicenter study. Also, due to the lack of necessary infrastructure for blinding, the trial is enabled.

Acronym

IRCT registration information

IRCT registration number: **IRCT20201124049480N1**
Registration date: **2021-03-28, 1400/01/08**
Registration timing: **prospective**

Last update: **2021-09-24, 1400/07/02**
Update count: **1**

Registration date

2021-03-28, 1400/01/08

Registrant information

Name

Mohammad Hossein Asgardoon

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-21, 1400/02/01

Expected recruitment end date

2021-09-21, 1400/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Levamisole efficacy in treatment of COVID-19 and comparing it to the common treatment: a Clinical Trial

Public title

Efficacy of Levamisol in Treating COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 years or older Positive RT PCR test for COVID-19 Full consent and acceptance of the patient or his companion for taking the drug Patient traceability Women should not become pregnant for 30 days after the end of the study patients should not take levamisole for five days before entering the study (because the half-life of the drug is 16 hours)

Exclusion criteria:

Another justifying cause (such as a bacterial or fungal infection) for the patient's symptoms Allergic reaction to levamisole Use of antibiotics other than those used to treat COVID-19 Shortness of breath due to cardiogenic pulmonary edema Lactation pregnancy Patients with unstable hemodynamics; History of cirrhosis, hepatitis, or severe liver disease, GFR less than 30 ml/min Patients receiving chemotherapy for cancer

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **365**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization (Permuted block randomization) will be used as the randomization method in this study. 6 quadruple blocks including AABB, ABAB, ABBA, BBAA, BABA, and BAAB are determined and then for each of the 4 patients, one of these 6 blocks will be used by a random number table. In fact, according to the order specified in each block, two patients will receive treatment A (treatment with levamisole) and two patients will receive treatment B (treatment without levamisole).

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

AJA University of Medical Sciences

Street address

Tehran - West Fatemi St. - Shahid Etemadzadeh St. AJA University of Medical Sciences of the Islamic Republic of Iran

City

Tehran

Province

Tehran

Postal code

1411718541

Approval date

2021-01-06, 1399/10/17

Ethics committee reference number

IR.AJAUMS.REC.1399.199

Health conditions studied

1

Description of health condition studied

outpatient covid19 infected individuals

ICD-10 code

U07.1

ICD-10 code description

COVID-19

Primary outcomes

1

Description

the general condition of the patient

Timepoint

Days 1,3,5,7,9,14

Method of measurement

Verbal Numeric Scale(VNS)

Secondary outcomes

1

Description

hospital admission

Timepoint

Day 1,3,5,7,9,14

Method of measurement

telephone

2

Description
mortality rate
Timepoint
Day 1,3,5,7,9,14
Method of measurement
telephone

3

Description
cough
Timepoint
Day 1,3,5,7,9,14
Method of measurement
telephone

4

Description
sore throat
Timepoint
Day 1,3,5,7,9,14
Method of measurement
telephone

5

Description
Dyspnea
Timepoint
Day 1,3,5,7,9,14
Method of measurement
telephone

6

Description
Myalgia
Timepoint
Day 1,3,5,7,9,14
Method of measurement
telephone

7

Description
Diarrhea
Timepoint
Day 1,3,5,7,9,14
Method of measurement
telephone

8

Description
vomiting
Timepoint
Day 1,3,5,7,9,14
Method of measurement
telephone

9

Description
nausea
Timepoint
Day 1,3,5,7,9,14
Method of measurement
telephone

10

Description
Anosmia
Timepoint
Day 1,3,5,7,9,14
Method of measurement
telephone

11

Description
dysgeusia
Timepoint
Day 1,3,5,7,9,14
Method of measurement
telephone

12

Description
headache
Timepoint
Day 1,3,5,7,9,14
Method of measurement
telephone

13

Description
fever
Timepoint
Day 1,3,5,7,9,14
Method of measurement
telephone

Intervention groups

1

Description
Intervention group: Levamisole 50 mg/day for ten days + routine management for covid19 based on national protocol (Hydroxychloroquine tablets 200 mg daily, acetaminophen 500 mg every 6 hours in case of fever, naproxen 500 mg every 8 hours in case of myalgia, diphenhydramine syrup 10 cc every 8 hours in case of sore throat and cough, etc.)
Category
Treatment - Drugs

2

Description

Control group: routine outpatient management for covid19 based on national protocol (Hydroxychloroquine tablets 200 mg daily, acetaminophen 500 mg every 6 hours in case of fever, naproxen 500 mg every 8 hours in case of myalgia, diphenhydramine syrup 10 cc every 8 hours in case of sore throat and cough, etc.)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Yaghmaei Health Center

Full name of responsible person
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Recruitment center

Name of recruitment center
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Recruitment center

Name of recruitment center
Moosiabad Health Center

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Recruitment center

Name of recruitment center
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Recruitment center

Name of recruitment center
Vavan Health Center

Full name of responsible person
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Recruitment center

Name of recruitment center
Akbarabad Health Center

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Recruitment center

Name of recruitment center
Health Center Number 10

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Recruitment center

Name of recruitment center
Farmanfarmayan Health Center

Full name of responsible person
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Recruitment center

Name of recruitment center
Shahid Vahedi Health Center

Full name of responsible person
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Yakhchiabad, 30 meters from the Amoozgar, next to the Women's Organization

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Recruitment center

Name of recruitment center
Meysam Health Center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Grant name

Grant code / Reference number

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

Title of funding source
Artesh 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
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assistant professor
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Person responsible for updating data

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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
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
All collected de-identified participant data sets are to be shared
When the data will become available and for how long
the data will be available if requested via E-mail after publishing the article
To whom data/document is available
scientists who are willing to have access to our data should show some proof they are working in similar areas, e.g by sending the proposal. after evaluating the files by the authors, the data will be sent at their discretion..
Under which criteria data/document could be used
if they are conducting similar researches and they intend to compare the efficacy of levamisol with other drugs. if they intend to increase the study population of our study

and add it to their own work. if they intend to perform an analysis to check if the results are correct.

From where data/document is obtainable

they can send an email to mh_asgardoon@yahoo.com

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

The applicant must first explain the reasons behind their request to use our data via an email and send the documents such as the proposal file, ethics committee or the grant number received from the their institute. After correspondence and confirmation, the data will be sent. The data of this study will be available after October 2021.

Comments