Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Assessment of effect of levamisole on pneumonia caused by COVID-19

Protocol summary

Study aim
Strengthen the non-specific (natural) immune system with levamisole, which leads to a reduction in mortality and complications from COVID 19.

Design
Randomized Double-Blind Controled Trial

Settings and conduct
Both groups are HRCT scanned at the start of the CT scan study. The CT scan is repeated a week later in both groups. Also, at the time of the start of the study, blood counts were performed on all patients and a week later, they were repeated. RT PCR is repeated in the first five weeks and if positive, it is repeated every three days to be negative. Patients in both groups also receive symptomatic therapies prescribed by the therapist.

Participants/Inclusion and exclusion criteria
Patients 18 years of age and older are studied after gaining informed consent. Previous respiratory illnesses: cancer, pregnancy, lactation, immunosuppressive drugs, organ transplants, autoimmune diseases, white blood cells less than 5,000 at baseline can be ruled out.

Intervention groups
The study was designed to be blind and randomized to investigate the effect of levamisole in patients with covid 19. In this study, 50 symptomatic patients (decreased olfactory; cough; sore throat) whose pharyngeal or oral swabs were positive for SARS Cov2 RT PCR: were randomly divided into two groups. The first group received 50 mg three times daily for levamisole and the second group received placebo.

Main outcome variables
The course of the disease; the need for hospitalization; changes in CT scan and when RT PCT is negative are compared in both groups. The starting point for complete recovery is with negative RT PCR or need for hospitalization. Patients are also screened for mortality requiring ECU, length of hospital stay, renal complications, and exacerbation of symptoms on CT scan.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20131215015805N2**
Registration date: **2020-05-04, 1399/02/15**
Registration timing: **registered_while_recruiting**

Last update: **2020-05-04, 1399/02/15**
Update count: **0**

Registration date
2020-05-04, 1399/02/15

Registrant information

Name
Payam Peymani

Name of organization / entity
Health Policy Research Center, Shiraz University of Medical Sciences, Shiraz, Iran

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-05-04, 1399/02/15

Expected recruitment end date
2020-06-04, 1399/03/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Assessment of effect of levamisole on pneumonia caused by COVID-19

Public title
Assessment of effect of levamisole on pneumonia caused by COVID-19

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
COVID-19 Patients moderate Lung Complication informed consent

Exclusion criteria:
Patients with WBC COUNT <6000 Platelet less than 100 thousand Patients with immune diseases Previous respiratory diseases Cancer Pregnancy Breast Feeding immunosuppressive medication organ transplant autoimmune disease

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
4

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **50**
More than 1 sample in each individual
Number of samples in each individual: **25**
after randomization, 25 patients alocated for each group.

Randomization (investigator's opinion)
Randomized

Randomization description
The patients will be randomized into two groups at a ratio of 1:1 using random allocation software

Blinding (investigator's opinion)
Double blinded

Blinding description
this a double-blinded study. patients and caregivers will be blinded. intervention and placebo agent will be given a caregiver according to the randomization protocol.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Cmmitte, Shiraz University of Medical Sciences

Street address
zand street,Shiraz University of Medical Sciences,7th floor

City
Shiraz

Province
Fars

Postal code
71345-1978

Approval date
2020-05-02, 1399/02/13

Ethics committee reference number
IR.SUMS.REC.1399.178

Health conditions studied

1

Description of health condition studied
Coronavirus infection

ICD-10 code
B34.2

ICD-10 code description
Coronavirus infection, unspecified

Primary outcomes

1

Description
Prevent the development of pneumonia caused by Convid19

Timepoint
one week

Method of measurement
CT scan

2

Description
Reduce the need for hospitalization

Timepoint
two week

Method of measurement
Measure the length of hospital stay

3

Description
Death

Timepoint
2 to 3 week

Method of measurement
Measuring mortality

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention group: 50 mg three times daily for levamisole for 5 days
Category
Treatment - Drugs

2

Description
Control group: Like levamisole, placebo will be given three times a day.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Hazrat Ali Asghar Hospital in Shiraz
Full name of responsible person
Dr mohsen moghadami
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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
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Dr Payam Peymani
Position
Assistant Professor and Director of Pharmacoepidemiology andPharmacoeconomics Group, Health Policy R
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Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Payam Peymani

Position

Pharm.D, PhD Student in Pharmacoepidemiology

Latest degree

Ph.D.

Other areas of specialty/work

Epidemiology

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Web page address

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

Statistical Results

When the data will become available and for how long

6 month after the project completion

To whom data/document is available

By obtaining a license from the ethics committee and for scientific and research use in coordination with the main researchers

Under which criteria data/document could be used

The data is for use in this design only. If necessary, after obtaining the necessary permits from the ethics committee

From where data/document is obtainable

To researchers responsible for responding to this plan

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

Written request Coordinated by the ethics committee 2 months

Comments