

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Oct 2020

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 Controlled 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

Country

Iran (Islamic Republic of)

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Email address

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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 allocated 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 and Pharmacoeconomics
Group, Health Policy R

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for scientific inquiries

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Full name of responsible person

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Person responsible for updating data

Contact

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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