Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 2026

Evaluation of levamizole on treatment of patients with COVID 19 infection: a controlled clinical trial study.

Protocol summary

Study aim
Evaluation of the effect of Levamisole on treatment of the patients with COVI-19 infection
Design
In this study every patient with diagnosis of COVID-19 and with sign and symptoms will be selected and will randomized in control and interventional groups. 20 patients will be selected with mild, moderate and sever condition (overall 60) and in every condition group 10 patients, will be randomized with block randomization method in control and interventional groups.
Settings and conduct
After randomzation, in interventional group levamizole 50 mg daily for 14 days will be administered in addition to standard therapy and in control group only standard therapy will be administered.
Participants/Inclusion and exclusion criteria
the patients with COVID 19 infection
Intervention groups
In this study the selected patients will be setelled into two groups . in interventional group levamizole will be administered and in the control group any drug will be given,
Main outcome variables
clinical status, Blood O2 saturation, Hemodynamic state

General information

Reason for update
Acronym
لوامیزول
IRCT registration information
IRCT registration number: **IRCT20181208041886N1**
Registration date: **2020-10-18, 1399/07/27**
Registration timing: **prospective**

Last update: **2020-10-18, 1399/07/27**
Update count: **0**

Registration date
2020-10-18, 1399/07/27

Registrant information
Name
Morteza Pourahmad
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-10-22, 1399/08/01
Expected recruitment end date
2021-03-17, 1399/12/27
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of levamizole on treatment of patients with COVID 19 infection: a controlled clinical trial study.

Public title
Levamizole in treatment of COVID19.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
age =or > 18 years Diagnosis of COVID19 infection was made by positive test for RtPCR on nasopharyngeal swab, Lung HRCT and the opinion of infectious diseases

specialist. informed consent of patient for study the possibility of patient follow up.

Exclusion criteria:

Another cause for signs and symptoms hypersensitivity to levamizole consumption of other antibiotics on the neck. Dyspnea Pregnancy breat feeding

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The selected patients on inclusion and exclusion criteria will be randomized in two experimental and control groups in 15 randomized block. In every block 4 patients will be setelled (2 patient as control and 2 as interventional). At first the physician will visit the patients and on the clinical criteria he/she decided that the disease is mild, moderate and / or sever and the patient will setelled in the blocks and groups (control or interventional).

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study the patients and the physician who evaluate the signs and symptoms of the patients are blinded about the therapy. To prevent of the bias the levamizole tablet will be give the patients accompanied with other drugs. On the other hand the assessor also will not be informed about the drugs of the patients.

Placebo

Not used

Assignment

Parallel

Other design features

nothing

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Sofeh Street

City

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Isfehan

Postal code

8189111491

Approval date

2020-06-22, 1399/04/02

Ethics committee reference number

IR.MUI.MED.REC.1399.246

Health conditions studied

1

Description of health condition studied

COVID19

ICD-10 code

U07.1

ICD-10 code description

U07.1 COVID-19, virus identified•U07.2 COVID-19, virus not identifiedoClinically-epidemiologically diagnosed COVID-19oProbable COVID-19 oSuspected COVID-19

Primary outcomes

1

Description

Discontinuation of fever

Timepoint

Daily

Method of measurement

evaluation by a physician

2

Description

improvement of dyspnea

Timepoint

Daily

Method of measurement

evaluation by physician

3

Description

decreasing of cogh

Timepoint

Daily

Method of measurement

evaluation by physician

4

Description

elevation of O2sat of the blood

Timepoint

Daily

Method of measurement

evaluation by physician

5

Description
blood presure improvement
Timepoint
Daily
Method of measurement
evaluation by physician

6

Description
pulse rate improvement
Timepoint
Daily
Method of measurement
evaluation by physician

Secondary outcomes

1

Description
improvement of the patient which has had COVOD-19>
Timepoint
14 days
Method of measurement
evaluation of the patient by a physician

Intervention groups

1

Description
Intervention group: the patients with diagnosis of COVID19 with be treated by tablet Levamisole 50 mg daily for 14 days in addition to standard therapies for these patients. the sign and symptoms of the patients will be evaluated daily.
Category
Treatment - Drugs

2

Description
Control group: the patient with diagnosis of COVID19 will give the standard therapies and without Levamisole.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Zahra Hospital
Full name of responsible person
Morteza Pourahmad
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Dr. Shaghayegh Haghjoo, Research assistant of Isfahan University of Medical Sciences
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Research assistant of Isfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Morteza Pourahmad
Position
Professor

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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
the article from this study will be distributed the effect of Levamisole on treatment of COVID 19 infection
When the data will become available and for how long
immediately after article publish
To whom data/document is available
Every body
Under which criteria data/document could be used
no condition
From where data/document is obtainable
published article
What processes are involved for a request to access data/document
No procedure
Comments
No comment