Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Evaluation of efficacy of pharmacotherapy treatment of COVID- 19 infection using oral Levamisole and Formoterol+Budesonide inhaler and comparison of this treatment protocol with standard national treatment of the disease

Protocol summary

Study aim
A- Finding effective and available treatment for COVID-19 patients B- Comparison of our treatment protocol with national standard, treatment protocol

Design
Two arm, parallel group, randomized double blind clinical trial

Settings and conduct
Hospitalized COVID-19 positive patients will be randomly divided into two groups of 15 patients in Vali Asr hospital of Fasa, One group will be test group and another will be control group according to the medical ethics guidelines.

Participants/Inclusion and exclusion criteria
All of the COVID-19 hospitalized patients with positive PCR and Chest CT-scan

Intervention groups
Control group will take national standard treatment medicines and test group will take Levamisole tablet 50 mg TDS and Budesonide+ Formoterol inhaler 1 puff every 12 hours as intervention drugs in addition to standard treatment. Standard treatment consists of Hydroxychloroquine equal to 400 mg in a single dose and Kaletra (Lopinavir / Ritonavir) 200/50 mg two tablets every 12 hours. Both groups will take standard treatment but in test group intervention drugs will be added.

Main outcome variables
Main variables are elimination of sign of disease like Cough, Fever and dyspnea. Elimination of Lymphopenia and negative result of PCR and chest CT-scan are other expected result of intervention.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200324046852N1**
Registration date: **2020-04-05, 1399/01/17**
Registration timing: **registered_while_recruiting**

Last update: **2020-04-05, 1399/01/17**
Update count: **0**

Registration date
2020-04-05, 1399/01/17

Registrant information

Name
Siamack Afazeli

Name of organization / entity
Nivan pharmed pharmaceutical Company

Country
Iran (Islamic Republic of)

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+98 21 6647 5335

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-04-01, 1399/01/13

Expected recruitment end date
2020-04-13, 1399/01/25

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of efficacy of pharmacotherapy treatment of

COVID- 19 infection using oral Levamisole and Formoterol+Budesonide inhaler and comparison of this treatment protocol with standard national treatment of the disease

Public title
Comparison of efficacy of oral Levamisole and Formoterol+Budesonide inhaler with standard treatment of Corona infection.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
COVID-19 positive patients with positive, PCR and chest CT scan
Exclusion criteria:
Patients with sever respiratory problems including patients with:1. Spo2<60%2. Severe respiratory distress3. Heamodynamic instabilitty 4. Acid base disturbance 5. Severe Anemia Patients with hepatic diseases Patients with Nervous system diseases
Age
No age limit
Gender
Both

Phase
2-3
Groups that have been masked

- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Eligible patients will be selected by the clinician. Each patient will be assigned an alphabetical code, a list of codes will be sent to the researcher. The researcher coded the codes from the random number table and assigned a new numeric code to each patient for each test and control group. These numerical codes will be used to form patient records and place the patient in the designed group.
Blinding (investigator's opinion)
Double blinded
Blinding description
All of the research team will be blind about the groups of study and position of patients in each group except of physician and main researcher. Files of patients which will be numbered using a random number table will be sent for analyzer of the study. Information about position of patients in the groups is masked from research team. Outcomes Assessor will receive the information of patients without any name in the file. Just when statistical analysis would be finished information of groups will be revealed.
Placebo
Not used
Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Fasa University of Medical Sciences
Street address
Fasa University of Medical Sciences, Ebne sina Sq.
City
Fasa
Province
Fars
Postal code
86688 - 74616
Approval date
2020-03-30, 1399/01/11
Ethics committee reference number
IR.FUMS.REC.1399.002

Health conditions studied

1

Description of health condition studied
Corona virus infection
ICD-10 code
U07.1
ICD-10 code description
COVID-19, confirmed by laboratory testing

Primary outcomes

1

Description
Chest CT-Scan response to treatment including dispersion size of Ground Glass area, bronchitis and consolidation.
Timepoint
Days 0-3-7
Method of measurement
CT scan apparatus

2

Description
Response to treatment in Lymphocytes count.
Timepoint
Daily
Method of measurement
By apparatus in diagnostic lab.

3

Description
Response to treatment for COVID-19 specific PCR test
Timepoint
Days 0-3-7
Method of measurement
Using PCR apparatus

4

Description
Response to treatment in O2 level and CO2 level in ABG or VBG test
Timepoint
Daily
Method of measurement
By apparatus in diagnostic lab.

Secondary outcomes

1

Description
Blood pressure response to treatment
Timepoint
daily
Method of measurement
By Sphygmomanometer

2

Description
Creatinine level during intervention
Timepoint
Daily
Method of measurement
By apparatus in diagnostic labs.

3

Description
Level of CRP (C reactive protein) in response to intervention
Timepoint
Daily
Method of measurement
By apparatus in diagnostic labs.

Intervention groups

1

Description
Intervention group:In this group along with the standard drugs according to the national guideline of treatment for COVID-19, patients will take Levamisole 50 mg TDS for 3-7 days, made by Poursina pharmaceutical Company and Budesonide+Formoterol 1 Puff every 12 hours made by Astra Zenca Company for 3-7 days. Brand name of Budesonide+Formoterol is Symbicort and it has two strength ; 160/4.5 and 320/9 mcg respectively. Decision about the used strength and dose of drug depends on the situation of the disease and will be made by physician.
Category
Treatment - Drugs

2

Description
Control group: This group just take standard drugs consist of Kaletra and Hydroxychloroquie. This national protocol would be taken as below: 1- Hydroxychloroquine sulfate 200 mg as a single dose. 2- Kaletra tablet (Lopinavir/ Ritonavir) 200/50 mg 2 tablets every 12 hoursfor atleast 5 days which can be extended to 14 days.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Vali Asr Hospital
Full name of responsible person
Dr. Jalal Karimi
Street address
Ebne Sina Square
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Fars
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86688 - 74616
Phone
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Email
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Web page address
http://www.fums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Fasa University of Medical Sciences
Full name of responsible person
Dr. Mojtaba Farjaam
Street address
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Email

farjam.md@gmail.com

Web page address

http://www.fums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Fasa 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

Fasa University of Medical Sciences

Full name of responsible person

Dr. Siamack Afazeli

Position

consultant

Latest degree

Medical doctor

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr.Siamack Afazeli

Position

Consultant

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

consultant

Latest degree

Medical doctor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Just some part of data which is deductible for health care staff will be shared.

When the data will become available and for how long

From the 17th of April till 17th of June 2020

To whom data/document is available

Just for medical proffesionals and managers of Ministry of health

Under which criteria data/document could be used

Following to written approval of Research deputy of Fasa University of medical sciences

From where data/document is obtainable

Research deputy of Fasa University of medical sciences

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

By correspondence with the research deputy of the University and after approval requested data will be sent.

Comments