

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Aug 2026

Evaluation of the efficacy of the triple combination of interferon beta-1B (IFN β -1b), chloroquine and Kaletra in the treatment and improvement of symptoms in patients with covid -19: Clinical trial.

Protocol summary

Study aim

The effectiveness of the triple combination of interferon beta-1B, chloroquine and Kaletra in the treatment and improvement of symptoms in patients with Covid 19 will be evaluated.

Design

A randomized and prospective clinical trial study with a control group and a sample size of 82 people using a Blocked randomization method

Settings and conduct

This study will be performed at Dr.Ganjavian Hospital in Dezful in patients who have received the covid -19 treatment regimen in accordance with the country guideline without interferon beta1b control group)and with interferon beta 1b ((intervention group).

Participants/Inclusion and exclusion criteria

Inclusion criteria: Individuals over 18 years of age whose covid-19 disease has been confirmed by PCR test and clinically severely ill. o2sat below 90% despite receiving oxygen Severe bilateral pulmonary involvement Satisfaction to participate in the study,Failure to receive any medication other than the standard protocol approved by the National Corona Therapy exclusion criteria:History of drug allergies to similar compounds Pregnancy and lactation.Infection with other microbial or viral infections,History of heart disease

Intervention groups

Intervention group Individuals Intervention group Approved nationally recommended hydroxychloroquine regimen as a single dose and then daily intake of Kaletra and in addition to the above treatment with interferon beta-1B (250 micrograms or 8 million subcutaneous units daily).Individuals in the control group receive only a single approved nationally recommended hydroxychloroquine regimen as a single dose and then daily consumption of Kaletra

Main outcome variables

Clinical efficacy according to clinical response based on blood oxygen saturation and changes in respiration rate).Laboratory findings(LDH levels and changes in liver enzymes).Duration of hospitalization and mortality rate

General information

Reason for update

Acronym

*

IRCT registration information

IRCT registration number: **IRCT20200921048786N1**

Registration date: **2020-11-11, 1399/08/21**

Registration timing: **registered_while_recruiting**

Last update: **2020-11-11, 1399/08/21**

Update count: **0**

Registration date

2020-11-11, 1399/08/21

Registrant information

Name

leila masoudiyekta

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 4242 6013

Email address

masoudiyekta@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-22, 1399/07/01

Expected recruitment end date

2020-12-20, 1399/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the efficacy of the triple combination of interferon beta-1B (IFN β -1b), chloroquine and Kaletra in the treatment and improvement of symptoms in patients with covid -19: Clinical trial.

Public title

Evaluation of the effect of interferon beta-1b in the treatment of COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Individuals over 18 years of age whose covid-19 disease has been confirmed by PCR test (PCR specification of the test from the Iranian manufacturer - Pishtaz Teb and performed by molecular method) and clinically severely ill o2sat below 90% despite receiving oxygen Severe bilateral pulmonary involvement Satisfaction to participate in the study Failure to receive any medication other than the standard protocol approved by the National Corona Therapy

Exclusion criteria:

History of drug allergies to similar compounds Pregnancy and lactation Infection with other microbial or viral infections History of heart disease

AgeFrom **18 years** old**Gender**

Both

Phase

3

Groups that have been masked*No information***Sample size**Target sample size: **82****Randomization (investigator's opinion)**

Randomized

Randomization description

82 eligible patients will be divided into two groups of 41 people. In 41 people in the intervention group (approved nationally approved hydroxychloroquine regimen as a single dose and then daily consumption of coltra and in addition to the above treatment with interferon beta-one B (at a dose of 250 micrograms or 8 million subcutaneous units every other day). Interferon Beta is one of the drugs of Iran Pharmaceutical Company. In order to randomly assign people to two groups and to ensure the balance of the number of people in the groups, the Block Randomization method will be used. In this study, blocks of four sizes will be created in which half of the people in each block will be randomly placed in one group and half in the other group. To do this, first identify all possible states in which half of the subjects are assigned to group A (interferon group) and the other

half to group B (control group): 1-AABB 2-BBAA 3-ABAB 4-BABA 5-ABBA 6-BAAB Then, each of the 4 blocks will be assigned one of the digits 1 to 6, and from blocks 1 to 6, simple combinations (blocks) will be performed randomly using a table of random numbers. Selection of blocks will continue until 82 patients are divided into two groups of 41 intervention and control patients. The selected blocks are recorded in a sequence, and according to this sequence, the subjects will be assigned to one of the two groups A or B. The resulting sequence is first recorded in a randomized block method, and each of the letters A and B in the generated sequence, which indicates interferon reception, will be assigned a number from 1 to 82. Due to the unpredictability of the sequence created by the randomized block method, all researchers except the main researcher will be unaware of the size and order of the blocks. Both groups will be given basic treatment and in addition to the basic treatment, the intervention group will be given interferon.

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**

Ethics committee of Dezful University of Medical Sciences

Street address

Azadegan Boulevard

City

dezful

Province

Khouzestan

Postal code

6461653476

Approval date

2020-09-21, 1399/06/31

Ethics committee reference number

IR.DUMS.REC.1399.031

Health conditions studied**1****Description of health condition studied**

COVID-19

ICD-10 code

U07.1

ICD-10 code description

Primary outcomes

1

Description

Clinical efficacy according to clinical response based on blood oxygen saturation

Timepoint

Daily

Method of measurement

Pulse oximetry

2

Description

LDH levels

Timepoint

Three times a week

Method of measurement

laboratory test

3

Description

Duration of hospitalization

Timepoint

End of treatment

Method of measurement

Patient file

4

Description

Mortality rate

Timepoint

Daily

Method of measurement

Patient file

5

Description

Changes in liver enzymes

Timepoint

twice a week

Method of measurement

laboratory test

6

Description

Clinical efficacy of treatment regimen based on changes in respiratory rate

Timepoint

Daily

Method of measurement

Patient record and clinical examination

Secondary outcomes

1

Description

Lung involvement status

Timepoint

Weekly

Method of measurement

Interpretation of CT scan

Intervention groups

1

Description

Individuals in the intervention group approved by the nationally approved hydroxychloroquine regimen as a single dose and then daily administration of Kaletra and in addition to the above treatment with interferon beta-one B (at a dose of 250 micrograms or 8 million subcutaneously every other day). Beta is a subsidiary of Iran Pharmaceutical Company.

Category

Treatment - Drugs

2

Description

Control group: Individuals in the control group receive only the recommended national hydroxychloroquine diet as a single dose and then daily consumption of Coltra.dose and then daily consumption of Kaletra.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Ganjavian Hospital, Dezful

Full name of responsible person

Leila Masoudi Yekta

Street address

Azadegan Boulevard, Dezful University of Medical Sciences

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DEZFUL

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masoudiyekta@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Dezfoul University of Medical Sciences

Full name of responsible person

Leila Masoudi Yekta

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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

Dezfoul 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**

Dezfoul University of Medical Sciences

Full name of responsible person

Leila Masoudi Yekta

Position

Faculty

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Person responsible for updating data**Contact****Name of organization / entity**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The results of the study will be published along with the statistical analysis and method of the study.

When the data will become available and for how long

Access to the data will be possible at the time of publication of the results of the study

To whom data/document is available

University centers, medical staff and research centers

Under which criteria data/document could be used

For research and practical purposes

From where data/document is obtainable

Leila Masoudi Yekta - School of Nursing, Dezful University of Medical Sciences

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

The person in charge of the study will respond within 10 days upon receiving the application form.

Comments