Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 coltra 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
Age
From **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

COVID-19, virus identified

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 Boulevar، Dezful University of Medical Sciences
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Dezfoul University of Medical Sciences
Full name of responsible person
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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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Azadegan Boulevard, Dezful University of Medical Sciences
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Person responsible for scientific inquiries

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Person responsible for updating data

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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