# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

31 May 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**
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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**
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

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## Person responsible for updating data

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**Phone**
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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**