

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Effect of interferon in the treatment of covid

Protocol summary

2023-10-06, 1402/07/14

Study aim

Comparison of blood oxygen saturation percentage in two groups of interferon received covid patients and control patients Comparison of length of hospitalization between intervention and control groups Comparison of ICU hospitalization rate in two intervention and control groups Comparison of 28-day mortality rate of two intervention and control groups

Design

Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 60 patients. The rand function of Excel software was used for randomization

Settings and conduct

Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 60 patients. The rand function of Excel software was used for randomization

Participants/Inclusion and exclusion criteria

Patients with Crona pneumonia needed to be hospitalized

Intervention groups

Patients who received interferon in addition to common corona treatment

Main outcome variables

Hospitalization period Death rate Effect on blood oxygen Effect on the need for ICU Care

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230930059562N1**

Registration date: **2023-10-06, 1402/07/14**

Registration timing: **retrospective**

Last update: **2023-10-06, 1402/07/14**

Update count: **0**

Registration date

Registrant information

Name

Roya Rahmani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 912 465 5334

Email address

roya.rahmani89@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-21, 1399/11/02

Expected recruitment end date

2021-07-23, 1400/05/01

Actual recruitment start date

2021-01-21, 1399/11/02

Actual recruitment end date

2021-07-22, 1400/04/31

Trial completion date

2021-09-22, 1400/06/31

Scientific title

Effect of interferon in the treatment of covid

Public title

Effect of interferon in the treatment of covid

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with Covid pneumonia who needs to hospitalised

Exclusion criteria:

Oxygen saturation percentage above 89%

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **80**

Actual sample size reached: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

A simple randomization method using a table of random numbers. Patients with a positive PCR test who were volunteered to participate in the project were included in the project. Each patient was assigned a random code. Kendall's table was designed by the computer, which has rows and columns, and the computer itself put numbers side each other randomly, a row and a column were randomly selected, and the intersection point of the row and column was sampled as the starting point. Then the plus sign was drawn and all the numbers that were on it were selected as sample members of the intervention group. This process continued until 40 people were selected and other people were placed in the control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patients were divided into two groups of 40 people, and the first intervention group received interferon beta in addition to the usual medical regime of Corona (Hydroxychloroquine and Kaletra) and the second group (control) only received the usual medical regime. None of the groups knew which category they were in. The patients received the drugs in the form of packs by one of the colleagues of the project and were blinded to the drugs in the pack.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary IDs

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Faculty of Medicine - Shahid Beheshti University of Medical Sciences, Tehran, Quds town (West), between South Flamek and Zarafshan, Simai Iran St. - Ministry of Health, Treatment and Medical Education Central

Headquarters

City

Tehran

Province

Tehran

Postal code

4631 19395

Approval date

2023-09-04, 1402/06/13

Ethics committee reference number

IR.SBMU.MSP.REC.1402.282

Health conditions studied

1

Description of health condition studied

Covid pneumonia

ICD-10 code

B97.2

ICD-10 code description

Coronavirus as the cause of disease

Primary outcomes

1

Description

Duration of hospitalization and ambient blood oxygen saturation percentage and duration of ICU needed in patients who receive interferon

Timepoint

All the time spent in hospital

Method of measurement

Investigating the effect of interferon in the treatment of corona by calculating the percentage of ambient blood oxygen and the duration of hospitalization by pulse oximetry and observing the patient's clinical condition

Secondary outcomes

empty

Intervention groups

1

Description

"Intervention group:" people receiving Recigen brand interferon beta with a dose of 12m IU EQ daily for 5 days along with other common corona treatments including hydroxychloroquine 200 every 12 hours and Kaletra 400 (ritonavir/lopinavir) daily

Category

Treatment - Drugs

2

Description

:"Control group:" Hydroxychloroquine 200 mg every 12 hours and Kaletra (lopinavir/ritonavir) at a dose of 400 mg daily on all days of hospitalization

Category
Treatment - Drugs

Type of organization providing the funding
Academic

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam hosein hospital
Full name of responsible person
Roya Rahmani
Street address
Imam Hossein Square, Shahid Madani St
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Imam hossein hospital
Full name of responsible person
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Imam hossein square ,Shahid madani St
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Phone
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Email
Info@sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Imam hossein hospital
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

Person responsible for general inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Roya Rahmani
Position
Doctor
Latest degree
Medical doctor
Other areas of specialty/work
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Person responsible for updating data

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Roya.rahmani89@gmail.com

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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Investigating the effect of interferon in the treatment of corona by calculating the percentage of ambient blood oxygen and the duration of hospitalization by pulse oximetry and observing the patient's clinical status and vital signs

When the data will become available and for how long

From the start of the project to the publication of the results

To whom data/document is available

Doctors active in the treatment of corona, universities of medical sciences of the country

Under which criteria data/document could be used

To be used in comparison with other corona treatment methods

From where data/document is obtainable

Roya rahmani

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

By contacting the project manager

Comments