

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation and comparison of the effect of two interferon alpha and beta antiviral drugs on the prognosis of patients with COVID 19

Protocol summary

Study aim

Determination and comparison of the effect of two antiviral drugs (interferon beta 1A and interferon alpha 2A) on the prognosis of patients with COVID 19

Design

Randomized, Placebo-Controlled Clinical Trial with 80 patients

Settings and conduct

This study will conduct on patients with COVID- 19 who admitted in the Emam Hasan hospital of Bojnord and Shariati hospital of Mashhad. Eligible patient will be randomized in 4 groups, two groups will receive interferon (alpha or beta) and two group will receive placebo. the subjects, investigator, and the data analysts will remain blinded

Participants/Inclusion and exclusion criteria

Inclusion criteris: •Adult over 18 years and unpregnant women •Clinical diagnosis of COVID-19 exclusion criterion •History of allergy to human albumin or interferon

Intervention groups

Intervention group 1: patients who will receive standard care plus 4 consecutive doses of intramuscular injection of beta-interferon (each vial contains 30 micrograms of interferon equivalent to 6 million international units
Intervention group 2: patients who will receive standard care plus 2 doses of subcutaneous injection of Alpha-interferon (each vial contains 180 micrograms of interferon) with 7 day interval. Control group 1: patients who will receive standard care plus beta-interferon placebo Control group 2: patients who will receive standard care plus alpha-interferon placebo

Main outcome variables

Body temperature •Respiratory rate •The ratio of arterial oxygen partial pressure to fractional inspired oxygen
•Blood gas level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20161206031256N3**
Registration date: **2020-06-02, 1399/03/13**
Registration timing: **registered_while_recruiting**

Last update: **2020-06-02, 1399/03/13**

Update count: **0**

Registration date

2020-06-02, 1399/03/13

Registrant information

Name

Maryam Khoshkhui

Name of organization / entity

Mashhad university

Country

Iran (Islamic Republic of)

Phone

+98 51 3801 2770

Email address

khoshkhui@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-23, 1399/03/03

Expected recruitment end date

2020-07-21, 1399/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation and comparison of the effect of two interferon alpha and beta antiviral drugs on the prognosis of

patients with COVID 19

Public title

Using interferon to treat COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Adult over 18 years Clinical diagnosis of COVID-19

Exclusion criteria:

History of allergy to human albumin or interferon

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator
- Data analyster

Sample size

Target sample size: **76**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple Randomization using the envelope placement method

Blinding (investigator's opinion)

Triple blinded

Blinding description

Eligible patient will be randomized in 4 groups, two groups will receive interferon (alpha or beta) and two group will receive placebo. the subjects, investigator, and the data analysts will remain blinded

Placebo

Used

Assignment

Crossover

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Regional Ethics Committee Mashhad University of Medical Sciences

Street address

Ghoreishi Building, Next to the cinema Hoveizeh , University Avenue, Mashhad, Iran.

City

Mashhad

Province

Razavi Khorasan

Postal code

91735-951

Approval date

2020-05-10, 1399/02/21

Ethics committee reference number

IR.MUMS.REC.1399.219

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

COVID-19

ICD-10 code

RA01.0.

ICD-10 code description

the code for the confirmed diagnosis of COVID-19

Primary outcomes**1****Description**

Body temperature

Timepoint

Before intervention, on day of 1 until discharge with 3 day interval

Method of measurement

Thermometer, Celsius

2**Description**

Respiratory rate

Timepoint

Before intervention, on day of 1 until discharge with 3 day interval

Method of measurement

Pulse oximeter, Breaths per minute

3**Description**

The ratio of arterial oxygen partial pressure to fractional inspired oxygen

Timepoint

Before intervention, on day of 1 until discharge with 3 day interval

Method of measurement

Ventilator, Millimeter of mercury (mmHg)

4**Description**

Blood gas level

Timepoint

Before intervention, on day of 1 until discharge with 3 day interval

Method of measurement

Blood Gas Analyzer, percent

Secondary outcomes

1

Description

Lymphocyte count

Timepoint

Before intervention, on day of 1 until discharge, with 3 day interval

Method of measurement

Cell counter, Cell per milliliter

2

Description

Lymphocyte count

Timepoint

Before intervention, on day of 1 until discharge, with 3 day interval

Method of measurement

Cell counter, Cell per milliliter

3

Description

C-reactive protein level

Timepoint

Before intervention, on day of 1 until discharge, with 3 day interval

Method of measurement

Clinical Biochemistry Analyzer, milligram per deciliter

4

Description

Erythrocyte Sedimentation Rate

Timepoint

Before intervention, on day of 1 until discharge, with 3 day interval

Method of measurement

ESR analyzer, millimeter per hour

5

Description

Alanine aminotransferase Level

Timepoint

Before intervention, on day of 1 until discharge, with 3 day interval

Method of measurement

Autoanalyzer, Unit per liter

6

Description

Aspartate aminotransferase Level

Timepoint

Before intervention, on day of 1 until discharge, with 3 day interval

Method of measurement

Autoanalyzer, Unit per liter

7

Description

Total/ conjugated bilirubin levels

Timepoint

Before intervention, on day of 1 until discharge, with 3 day interval

Method of measurement

Autoanalyzer, Milligram per deciliter

8

Description

Creatinine

Timepoint

Before intervention, on day of 1 until discharge, with 3 day interval

Method of measurement

Autoanalyzer, Milligram per deciliter

9

Description

Creatine kinase myocardial band (CK-MB)

Timepoint

Before intervention, on day of 1 until discharge, with 3 day interval

Method of measurement

Autoanalyzer, international unit per liter

10

Description

Troponin

Timepoint

Before intervention, on day of 1 until discharge, with 3 day interval

Method of measurement

enzyme-linked immunosorbent assay, nanogram per millilitere

11

Description

Hospitalization time

Timepoint

Admission time until discharge

Method of measurement

Day

12

Description

Mortality rate

Timepoint

on day of 14 and 28 after intervention

Method of measurement

Mortality formula

13

Description

National early warning score 2

Timepoint

On day of 1 and 7 after intervention

Method of measurement

Formula, scoring

14

Description

Polymerase chain reaction

Timepoint

on day of 1 and 14 after intervention (if PCR on day of 1 was positive)

Method of measurement

Thermocyclers

15

Description

Chest scan

Timepoint

On day of 10 after intervention

Method of measurement

Scan

Intervention groups

1

Description

Intervention group 1: patients who will receive standard care plus 4 consecutive doses of intramuscular injection of beta-interferon (each vial contains 30 micrograms of interferon equivalent to 6 million international units

Category

Treatment - Drugs

2

Description

Intervention group 2: : patients who will receive standard care plus 2 doses of subcutaneous injection of Alpha-interferon (each vial contains 180 micrograms of interferon) with 7 day interval.

Category

Treatment - Drugs

3

Description

Control group 1: patients who will receive standard care plus beta-interferon placebo

Category

Placebo

4

Description

Control group 2: patients who will receive standard care plus alpha-interferon placebo

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati Hospital

Full name of responsible person

Maryam khoshkhui

Street address

Emam reza 1, Torghabeh, wakil abad Blv, Mashhad, Razavi Khorasan Province, Iran

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2

Recruitment center

Name of recruitment center

Imam Hassan hospital

Full name of responsible person

Maryam Khoshkui

Street address

Imam Hassan hospital, Pardis Town Bojnourd, North Khorasan, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

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Vice Chancellor for Research and Technology University, Ghoreishi Building, University Avenue, next to the cinema Hoveize, , Mashhad, Razavi Khorasan

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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

Mashhad University of Medical Sciences

Proportion provided by this source

50

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

2

Sponsor

Name of organization / entity

CinnaGen company

Full name of responsible person

Borna Payandehmehr

Street address

No.2 , 7thSt., Simaye Iran St., Shahrak Gharb, Tehran, IRAN

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3165933155

Phone

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Email

cinnagen@cinnagen.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

CinnaGen company

Proportion provided by this source

25

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Industry

3

Sponsor

Name of organization / entity

Pooyesh Darou company

Full name of responsible person

Khakinezhad

Street address

NO. 13, 5th Ave, Fatemi St, Tehran, Iran

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1415763863

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+98 21 8899 7248

Email

info@pooyeshdarou.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Pooyesh Darou company

Proportion provided by this source

25

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Industry

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

maryam Khoshkhui

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Clinical immunology and Allergy

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Master
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available