Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 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 Ǝmam 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 COVD-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

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Iran (Islamic Republic of)

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khoshkhuim@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 analyser

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 mililitere

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, vakil 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

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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

Street address

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

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

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3165933155

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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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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

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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)
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