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 伊朗 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
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 milliliter

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

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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

3
Sponsor
Name of organization / entity
CinnaGen company
Full name of responsible person
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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

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
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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