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 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
Country
Iran (Islamic Republic of)
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+98 51 3801 2770
Email address
khoshkhui@mums.ac.ir

Recruitment status
recruiting

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 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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Mashhad
Province
Razavi Khorasan
Postal code
9351899983
Phone
+98 51 3551 0010
Fax
Email
dshh.pr@mums.ac.ir

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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Bojnourd
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North Khorasan
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9351899983
Phone
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Imamhasan@nkums.ac.ir

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
City
Mashhad
Province
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, 7th St., Simaye Iran St., Shahrak Gharb, Tehran, IRAN
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Province
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Postal code
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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
Phone
+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
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Postal code
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Person responsible for scientific inquiries

Contact
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Full name of responsible person
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Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for updating data

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Master
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Immunology
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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