Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Oct 2020

Plasma exchange in patients with COVID-19 to reduce viral load and inflammatory molecules

Protocol summary

Study aim

Regard to Coronavirus disease outbreak and lack of specific vaccine and drugs, designing of effective therapeutic strategies is major public health priorities. In this prospective, phase II trial, we are going to evaluate the safety and efficacy of plasma exchange with the equal volume of colloidal solution containing 4-5% albumin, fresh frozen plasma, and convalescent plasma in COVID-19 patients to reduce viral load and inflammatory molecules

Design

This is a prospective, phase 2 study that will be done on 10 patients with CoVID-19

Settings and conduct

This study will conduct on patients with COVID- 19 who admitted in the Taleghani hospital of Tehran. Approximately 1500-2000 milliliter of patient's plasma will be exchanged with the equal volume of colloidal solution containing 4-5% albumin and fresh frozen plasma (FFP) for two consecutive days. In the next step, plasma therapy will be done with convalescent plasma from patients who recovered from COVID-19.

Participants/Inclusion and exclusion criteria

Inclusion criteria, 18 to 65 years, Positive Real Time-Polymerase Chain Reaction test for COVID-19 , exclusion criteria, History of renal disease and dialysis

Intervention groups

Treatment is preformed in two steps; step one, plasma exchange with colloidal solution containing 4-5% human albumin and fresh frozen plasma. Step two, plasma therapy with convalescent plasma.

Main outcome variables

Size of lesion on lung, Body temperature, The ratio of arterial oxygen partial pressure (PaO2 in mmHg) to fractional inspired oxygen (FiO2 expressed as a fraction, not a percentage), Respiratory rate, Serum levels of Interleukin 1,6,10, and Tumor necrosis factor alpha, Negative Real Time- Polymerase Chain Reaction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200416047099N2**
Registration date: **2020-07-04, 1399/04/14**
Registration timing: **registered_while_recruiting**

Last update: **2020-07-04, 1399/04/14**
Update count: **0**

Registration date

2020-07-04, 1399/04/14

Registrant information

Name

Abbas Hajifathali

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2303 1657

Email address

a.hajifathali@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-21, 1399/04/01

Expected recruitment end date

2020-09-20, 1399/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Plasma exchange in patients with COVID-19 to reduce viral load and inflammatory molecules

Public title
Plasma exchange in COVID-19 patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Positive Real Time-Polymerase Chain Reaction test of COVID-19
Exclusion criteria:
History of renal disease and dialysis
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **10**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Vice-chancellor in research affairs- Shahid beheshti university of medical sciences
Street address
7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
19839-63113
Approval date
2020-06-16, 1399/03/27
Ethics committee reference number
IR.SBMU.MSP.REC.1399.118

Health conditions studied

1

Description of health condition studied
Coronavirus disease -19 (COVID-19)
ICD-10 code
RA01.0
ICD-10 code description
The confirmed diagnosis of COVID-19

Primary outcomes

1

Description
Size of lesion on lung
Timepoint
On day 1, day 4,day 7, day 14, and day 28 after the treatment
Method of measurement
CT scan, Millimeter

2

Description
Body temperature
Timepoint
On day 1, day 4,day 7, day 14, and day 28 after the treatment
Method of measurement
Thermometer, Celsius

3

Description
The ratio of arterial oxygen partial pressure (PaO2 in mmHg) to fractional inspired oxygen (FiO2 expressed as a fraction, not a percentage)
Timepoint
On day 1, day 4,day 7, day 14, and day 28 after the treatment
Method of measurement
Ventilator, Millimeter of mercury (mmHg)

4

Description
Respiratory rate
Timepoint
On day 1, day 4,day 7, day 14, and day 28 after the treatment
Method of measurement
Pulse oximeter, Breaths per minute

5

Description
Serum level of Interleukin 1
Timepoint
Before and after the treatment
Method of measurement
Enzyme-linked immunosorbent assay (ELISA), Milligrams

per deciliter

6

Description
Serum level of Interleukin 6
Timepoint
Before and after the treatment
Method of measurement
Enzyme-linked immunosorbent assay (ELISA), Milligrams per deciliter

7

Description
Serum level of Interleukin 10
Timepoint
Before and after the treatment
Method of measurement
Enzyme-linked immunosorbent assay (ELISA), Milligrams per deciliter

8

Description
Serum level of tumor necrosis factor alpha
Timepoint
Before and after the treatment
Method of measurement
Enzyme-linked immunosorbent assay (ELISA), Milligrams per deciliter

Secondary outcomes

1

Description
Anti- corona virus immune globulin G level
Timepoint
Before and after the treatment
Method of measurement
Enzyme-linked immunosorbent assay (ELISA), Milligrams per deciliter

2

Description
Mortality rate
Timepoint
During the study
Method of measurement
Mortality formula

3

Description
Oxygen saturation
Timepoint
On day 1, day 4, day 7, day 14, and day 28 after the treatment
Method of measurement
Pulse oximetry

4

Description
Lymphocyte count
Timepoint
On day 1, day 4, day 7, day 14, and day 28 after the treatment
Method of measurement
Cell counter, Cell per milliliter

5

Description
CD3+ cell count
Timepoint
On day 1, day 4, day 7, day 14, and day 28 after the treatment
Method of measurement
Flowcytometer, Cell per milliliter

6

Description
CD4+ cell count
Timepoint
On day 1, day 4, day 7, day 14, and day 28 after the treatment
Method of measurement
Flowcytometer, Cell per milliliter

7

Description
CD8+ cell count
Timepoint
On day 1, day 4, day 7, day 14, and day 28 after the treatment
Method of measurement
Flowcytometer, Cell per milliliter

8

Description
Alanine aminotransferase level
Timepoint
On day 1, day 4, day 7, day 14, and day 28 after the treatment
Method of measurement
Autoanalyzer, Unit per liter

9

Description
Aspartate aminotransferase level
Timepoint
On day 1, day 4, day 7, day 14, and day 28 after the treatment
Method of measurement
Autoanalyzer, Unit per liter

10

Description
Total bilirubin level

Timepoint
On day 1, day 4, day 7, day 14, and day 28 after the treatment
Method of measurement
Autoanalyzer, Milligram per deciliter

11

Description
Direct bilirubin level
Timepoint
On day 1, day 4, day 7, day 14, and day 28 after the treatment
Method of measurement
Autoanalyzer, Milligram per deciliter

Intervention groups

1

Description
Intervention group: Plasma exchange (1.5 to 2 liter) with colloidal solution containing 4-5% albumin and fresh frozen plasma (FFP) for two consecutive days, and plasma therapy with convalescent plasma for one day.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Taleghani Hospital
Full name of responsible person
Abbas Hajifathali
Street address
Shahid A'rabi Ave, Yemen Ave, Shahid Chamran Hwy, Tehran
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1985711151
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Fax
Email
taleghanihospital@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Nasrin khateri
Street address
7th Floor, Bldg No.2 SBUMS, Shahid Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran.
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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
Shahid Beheshti University of Medical Sciences
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
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Abbas Hajifathali
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
Hematology
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Shahid Arabi Ave, Yemen Ave, Shahid Chamran Hwy, Tehran
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Person responsible for scientific inquiries

Contact

Name of organization / entity
Taleghani hospital
Full name of responsible person
Elham Roshandel
Position
Researcher
Latest degree
Ph.D.
Other areas of specialty/work
Cell Therapy
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Person responsible for updating data

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Haniye Ghaffari-nazari
Position
PhD student
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Master
Other areas of specialty/work
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