

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)

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+98 21 2303 1657

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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

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7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran

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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

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Full name of responsible person

Nasrin khateri

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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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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

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Position

PhD student

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Master

Other areas of specialty/work

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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