Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Oct 2026

Evaluation of the therapeutic effects of Convalescent Plasma (CP) of recovered people from Covid-19 in improving clinical and laboratory symptoms of hospitalized patients

Protocol summary

Study aim

Evaluation of the therapeutic effects of Convalescent Plasma (CP) of recovered people from Covid-19 in improving clinical and laboratory symptoms of hospitalized patients

Design

The clinical trial with a control group, with parallel groups, non-randomized, single-center. The sample size is 12 patients (consist of 2 groups of 6 control and intervention).

Settings and conduct

This study will be performed at Kosar hospital in Semnan. Convalescent plasma from COVID-19 recovered people will be injected to hospitalized patients suffering from COVID-19.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Complete resolution of COVID-19 disease symptoms at least 14 days prior to donation; Donors do not have a history of blood or blood product transfusion; COVID-19 neutralizing antibody titers be greater than 1:320 (If possibly checked); Negative results for COVID-19 by PCR; Respiratory frequency ≥ 30/min. Exclusion criteria: Negative real-time PCR from respiratory secretions or blood within 48 h prior to CP transfusion; History of allergic reaction to blood or plasma products; Known IgA deficiency.

Intervention groups

Intervention group: Administration of 2 units of intravenous CP (Convalescent Plasma obtained from COVID-19 recovered people thorough plasmapheresis). Each unit of plasma that is collected from one different donor will be given over 2 h with an interval of 1 h between the two units. Control group: Patients with COVID-19 will receive conventional treatment.

Main outcome variables

Checking the amount of ventilation; White blood cell count, CRP in patients with COVID-19; Percentage of T CD8 in peripheral blood; Percentage of T CD4 in peripheral blood; C-Reactive Protein (CRP) in patients with COVID-19

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151228025732N53**
Registration date: **2020-04-10, 1399/01/22**
Registration timing: **prospective**

Last update: **2020-04-10, 1399/01/22**
Update count: **0**

Registration date

2020-04-10, 1399/01/22

Registrant information

Name

Alireza Emadi

Name of organization / entity

Semnan University of Medical Sciences, Semnan, Iran

Country

Iran (Islamic Republic of)

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+98 23 3345 1336

Email address

are20935@semums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-20, 1399/02/01

Expected recruitment end date

2020-06-20, 1399/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the therapeutic effects of Convalescent Plasma (CP) of recovered people from Covid-19 in improving clinical and laboratory symptoms of hospitalized patients

Public title

Therapeutic effects of plasma of recovered people from COVID-19 on hospitalized patients with this disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

(As a plasma donor): Complete resolution of COVID-19 disease symptoms at least 14 days prior to donation. (As a plasma donor): Donors do not have a history of blood or blood product transfusion (As a plasma donor): COVID-19 neutralizing antibody titers be greater than 1:320 (If possibly checked) (As a plasma donor): The donor's age be between 25 and 55 years old (As a plasma donor): Negative results for COVID-19 by PCR (As a plasma donor): Be in suitable general health condition for plasmapheresis (As a plasma recipient): Patients admitted to the ICU who is receipt of mechanical invasive or non-invasive ventilation, partial pressure of arterial oxygen to fraction of inspired oxygen ratio < 300mmHg (93%). Current receipt of intravenous vasoactive medications to maintain mean arterial pressure >65 mmHg (As a plasma recipient): Respiratory frequency ≥ 30/min (As a plasma recipient): Laboratory-confirmed COVID-19 infection (by real time PCR).

Exclusion criteria:

(As a plasma recipient): Negative real-time PCR from respiratory secretions or blood within 48 h prior to CP transfusion (As a plasma recipient): History of allergic reaction to blood or plasma products (As a plasma recipient): Known IgA deficiency

Age

From **25 years** old to **55 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **12**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Semnan University of Medical Sciences

Street address

Semnan University of Medical Sciences, Basij boulevard, Semnan

City

Semnan

Province

Semnan

Postal code

3514799442

Approval date

2020-04-04, 1399/01/16

Ethics committee reference number

IR.SEMUMS.REC.1399.004

Health conditions studied

1

Description of health condition studied

COVID-19

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified

Primary outcomes

1

Description

Checking the amount of ventilation

Timepoint

Before intervention, 30 minutes after each step of intervention and daily

Method of measurement

Artificial respirator or ventilator

2

Description

White blood cell count, CRP in patients with COVID-19

Timepoint

Every 24 hours (Before and after intervention)

Method of measurement

Cell counter

3

Description
Percentage of T CD8 in peripheral blood
Timepoint
Before and after the intervention
Method of measurement
Evaluation of T CD8 percentage by Flow cytometry

4

Description
Percentage of T CD4 in peripheral blood
Timepoint
Before and after the intervention
Method of measurement
Evaluation of T CD4 percentage by Flow cytometry

5

Description
C-Reactive Protein (CRP) in patients with COVID-19
Timepoint
Every 24 hours (Before and after intervention)
Method of measurement
Rapid test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Administration of 2 units of CP (Convalescent Plasma obtained from COVID-19 recovered people thorough plasmapheresis) (IV). Each unit of plasma that is collected from one different donor will be given over 2 h with an interval of 1 h between the two units.
Category
Treatment - Drugs

2

Description
Control group: Patients with COVID-19 will receive conventional treatment.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Koesar hospital
Full name of responsible person
Parviz Kokhaei
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Amin street, Semnan
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Sponsors / Funding sources

1

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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
Semnan 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
Semnan University of Medical Sciences
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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
No - There is not a plan to make this available