# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

10 Jun 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)

**Phone**

+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
**Street address**
Amin street, Semnan
**City**
Semnan
**Province**
Semnan
**Postal code**
3514799442
**Phone**
+98 23 3344 1022
**Email**
are20935@gmail.com

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Semnan University of Medical Sciences
**Full name of responsible person**
Parviz Kokhaei
**Street address**
Semnan University of Medical Sciences, Basij boulevard, Semnan
**City**
Semnan
**Province**
Semnan
**Postal code**
3514799442
**Phone**
+98 23 3345 1336
**Email**
p_kokha@yahoo.com
**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
**Full name of responsible person**
Parviz Kokhaei
**Position**
Professor

**Latest degree**
Ph.D.
**Other areas of specialty/work**
Immunology
**Street address**
Semnan University of Medical Sciences, Basij boulevard, Semnan
**City**
Semnan
**Province**
Semnan
**Postal code**
3514799442
**Phone**
+98 23 3345 1336
**Email**
p_kokha@yahoo.com

## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Semnan University of Medical Sciences
**Full name of responsible person**
Parviz Kokhaei
**Position**
Professor
**Latest degree**
Ph.D.
**Other areas of specialty/work**
Immunology
**Street address**
Semnan University of Medical Sciences, Basij boulevard, Semnan
**City**
Semnan
**Province**
Semnan
**Postal code**
3514799442
**Phone**
+98 23 3345 1336
**Email**
p_kokha@yahoo.com

## Person responsible for updating data

**Contact**
**Name of organization / entity**
Semnan University of Medical Sciences
**Full name of responsible person**
Maral Hemati
**Position**
Academic Research Expert
**Latest degree**
Master
**Other areas of specialty/work**
Immunology
**Street address**
Semnan University of Medical Sciences, Basij boulevard, Semnan
**City**
Semnan
**Province**
Semnan
**Postal code**
3514799442
**Phone**
+98 23 3345 1336
**Email**
m.scientist1993@gmail.com

## 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