# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

19 Jun 2026

## The Effect of Convalescent Plasma Therapy on the Outcomes of Patients with 19-COVID

### Protocol summary

**Study aim**
Evaluation of convalescent plasma therapy in the treatment of patients with COVID-19 disease
**Design**
In this intervention study, 60 patients who have the criteria to enter the study are divided into two groups of 30 people by block randomization method. Patients are explained about treatment methods and their benefits and complications, and informed consent is obtained.
**Settings and conduct**
1. Convalescent plasma will be received from those recovering from COVID-19 disease previously hospitalized at Emam Khomeini, Emam Reza and Sabalan Hospitals 2- Convalescent Plasma received from volunteers will be infused to the patients with confirmed infection of COVID-19.
**Participants/Inclusion and exclusion criteria**
Inclusion criteria 1. Blood oxygenation saturation <90% 2. Abnormal lung CT scan 3. Significant shortness of breath 4. Fever 5. Not improving in the next 48 hours 6. There is no possibility of discharge of patient in the next 48 hours 7. Patient consent Exclusion criteria 1. The patient should not be connected to a ventilator . 2. The patient has not given consent.
**Intervention groups**
Intervention group: The recipient plasma group will receive 500 ml in 4 hours. Control group: The control group receives only routine treatment.
**Main outcome variables**
Reduction in all causes mortality; reduction of hospital stay

### General information

**Reason for update**
**Acronym**
**IRCT registration information**
IRCT registration number: **IRCT20150808023559N21**
Registration date: **2020-05-09, 1399/02/20**
Registration timing: **prospective**

Last update: **2020-05-09, 1399/02/20**
Update count: **0**
**Registration date**
2020-05-09, 1399/02/20

**Registrant information**
**Name**
Somaieh Matin
**Name of organization / entity**
Ardabil University of Medicine Sciences
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Iran (Islamic Republic of)
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**Recruitment status**
**Recruitment complete**
**Funding source**

**Expected recruitment start date**
2020-05-12, 1399/02/23
**Expected recruitment end date**
2020-08-22, 1399/06/01
**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
The Effect of Convalescent Plasma Therapy on the Outcomes of Patients with 19-COVID

**Public title**
The Effect of Convalescent Plasma Therapy on Patients with 19-COVID

**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Definitive diagnosis of Covid19 based on PCR Blood oxygen saturation less than 90% No recovery within 48 hours of routine treatment
**Exclusion criteria:**
History of allergic reactions to blood products injection
**Age**
No age limit
**Gender**
Both

**Phase**
1-2
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **60**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Patients are assigned randomly by blocking in one of the two specified groups and after selecting the envelope for each patient, before starting the treatment regimen envelope will be opened and based on the protocol, one of two methods will be selected.
**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 Ardabil University of Medical Sciences
**Street address**
Daneshghah street,Ardabil University of Medical Sciences
**City**
Ardabil
**Province**
Ardabil
**Postal code**
53141-56198
**Approval date**
2020-04-05, 1399/01/17
**Ethics committee reference number**
IR.ARUMS.REC.1399.052

## Health conditions studied

### 1

**Description of health condition studied**
covid 19
**ICD-10 code**
U07.1
**ICD-10 code description**
COVID-19

## Primary outcomes

### 1

**Description**
Reduction in all causes mortality
**Timepoint**
At the time of discharge of patients
**Method of measurement**
Patient documents

## Secondary outcomes

### 1

**Description**
Reduction of hospital stay
**Timepoint**
At the time of discharge of patients
**Method of measurement**
Patient documents

## Intervention groups

### 1

**Description**
Intervention group: Patients in the intervention group, in addition to routine treatment, will receive convalescent Plasma extracted from improved patients from 19-COVID in the amount of 500 ml over a period of 4 hours.
**Category**
Treatment - Drugs

### 2

**Description**
Control group: They only receive routine treatment.
**Category**
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Imam Khomeini and Sabalan Hospital of Ardabil
**Full name of responsible person**
Effat Irani Jam

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## Sponsors / Funding sources

**1**

**Sponsor**
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Shahab Bohlooli
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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**
Ardabil 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**
Ardabil University of Medical Sciences
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**Position**
assistant of professor
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**Other areas of specialty/work**
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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**
Not applicable

**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**
Not applicable

**Data Dictionary**
Not applicable