

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

20 Oct 2020

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

#### Protocol summary

Registration timing: **prospective**

#### Study aim

Evaluation of convalescent plasma therapy in the treatment of patients with COVID-19 disease

Last update: **2020-05-09, 1399/02/20**

Update count: **0**

#### 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.

#### Registration date

2020-05-09, 1399/02/20

#### Registrant information

##### Name

Somaieh Matin

##### Name of organization / entity

Ardabil University of Medicine Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 45 3373 3011

##### Email address

s.matin@arums.ac.ir

#### 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.

#### Recruitment status

**Recruitment complete**

#### Funding source

#### 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.

#### 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

#### 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

#### Scientific title

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

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20150808023559N21**

Registration date: **2020-05-09, 1399/02/20**

##### 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

**Street address**

Azadi Street

**City**

Ardabil

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**Postal code**

561577663

**Phone**

+98 45 3325 1402

**Email**

dr.jam733@gmail.com

## Sponsors / Funding sources

### 1

**Sponsor****Name of organization / entity**

Ardabil University of Medical Sciences

**Full name of responsible person**

Shahab Bohlooli

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research@arums.ac.ir

**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

**Full name of responsible person**

Effat Irani Jam

**Position**

assistant of professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Internal Medicine

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## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Ardabil University of Medical Sciences

**Full name of responsible person**

Somaieh Matin

**Position**

Assistant of Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Internal Medicine

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## Person responsible for updating data

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Ardabil University of Medical Sciences

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استادیار

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**Other areas of specialty/work**

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**Email**

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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