

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

25 Oct 2020

### Efficacy of convalescent plasma transfusion of COVID-19 survivors on the treatment of respiratory failure of these patients

#### Protocol summary

##### Study aim

Convalescent plasma of COVID-19 patients is effective for respiratory failure of these patients

##### Design

In 30 patients with confirmed COVID-19 with respiratory failure or ARDS, in addition to all antiviral and supportive treatments, 200-400 cc of convalescent plasma will be transfused. Improvement in SOFA score, oxygenation, P/F ratio, end organs failure and fever will be monitored.

##### Settings and conduct

After ABO compatibility of patient and donor, 200-250 cc of convalescent plasma will be transfused on the same that is prepared.

##### Participants/Inclusion and exclusion criteria

Criteria for entering the study: 1. Age over 18 years old  
2. Proven laboratory COVID-19 disease and positive PCR  
3. Existence of severe bilateral pneumonia in CT scan or chest x-ray  
4.  $Pao_2/fio_2 < 300$   
5. Oxygen therapy or mechanical ventilation.  
Exclusion criteria: 1. blood group incompatibility  
2. pregnancy

##### Intervention groups

COVID-19 patients treated with convalescent Plasma

##### Main outcome variables

1. Convalescent plasma transfusion  
2. P / F  
3. Blood pressure  
4. Kidney dysfunction  
5. Blood disorders  
6. consciousness  
7. SOFA score  
8. Mechanical ventilation duration  
9. Duration of hospitalization  
10. Hospital death

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200406046968N2**

Registration date: **2020-04-22, 1399/02/03**

Registration timing: **prospective**

Last update: **2020-04-22, 1399/02/03**

Update count: **0**

##### Registration date

2020-04-22, 1399/02/03

##### Registrant information

###### Name

Haleh Mikaeili

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 3329 6024

###### Email address

halehmikaeili@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-05-04, 1399/02/15

##### Expected recruitment end date

2020-07-05, 1399/04/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Efficacy of convalescent plasma transfusion of COVID-19 survivors on the treatment of respiratory failure of these patients

##### Public title

Efficacy of convalescent plasma transfusion of COVID-19 survivors on the treatment of respiratory failure of these patients

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

Age over 18 years Confirmed COVID-19 clinically and positive PCR Severe bilateral pulmonary involvement on CT scan or chest x-ray Pao<sub>2</sub>/Fio<sub>2</sub><300 Need for oxygen therapy or mechanical ventilation

**Exclusion criteria:**

Blood group incompatibility Pregnancy

**Age**

From **18 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **30**

**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**

Regional Research Ethics Committee (Humanities Studies)

**Street address**

3rd Floor, Central Building, University Street, Tabriz, Iran

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166614766

**Approval date**

2020-04-13, 1399/01/25

**Ethics committee reference number**

IR.TBZMED.REC.1399.018

**Health conditions studied****1****Description of health condition studied**

COVID-19 Disease

**ICD-10 code**

B34.2

**ICD-10 code description**

Coronavirus infection, unspecified site

**Primary outcomes****1****Description**

Effect of convalescent plasma

**Timepoint**

Blood and plasma will be taken from patients who have been symptom free for 14-17 days. If it is less than 14 days, the donor should have 2 negative tests in two different days.

**Method of measurement**

ELISA

**Secondary outcomes****1****Description**

Oxygenation

**Timepoint**

Daily until discharge or death

**Method of measurement**

ABG

**2****Description**

SOFA score

**Timepoint**

Daily until discharge or death

**Method of measurement**

Questionnaire

**3****Description**

Duration of mechanical ventilation

**Timepoint**

until discharge or death

**Method of measurement**

Questionnaire

**4****Description**

Duration of admission

**Timepoint**

Daily until discharge or death

**Method of measurement**

Questionnaire

**5****Description**

Mortality

**Timepoint**

Admission period  
**Method of measurement**  
patient's file

## Intervention groups

1

### Description

In 30 patients with respiratory failure and ARDS caused by COVID-19 undergoing mechanical ventilation or oxygen therapy, antivirals and supportive care therapies will be continued, and 200-400 cc of convalescent plasma will transfused for them.

### Category

Treatment - Other

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Imam Reza Hospital

#### Full name of responsible person

Haleh Mikaeili

#### Street address

3rd Floor, Central Building, University Street, Tabriz, Iran

#### City

Tabriz

#### Province

East Azarbaijan

#### Postal code

5166614756

#### Phone

+98 41 3334 7059

#### Email

info@imamreza.tbzmed.ac.ir

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Tabriz University of Medical Sciences

#### Full name of responsible person

Khosro Adibkia

#### Street address

3rd Floor, Central Building, University Street, Tabriz, Iran

#### City

Tabriz

#### Province

East Azarbaijan

#### Postal code

5166614766

#### Phone

+98 41 3335 7310

#### Email

research-vice@tbzmed.ac.ir

### Grant name

### Grant code / Reference number

### Is the source of funding the same sponsor organization/entity?

No

### Title of funding source

Tabriz university of medical science

### 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

Tabriz University of Medical Sciences

#### Full name of responsible person

Haleh Mikaeili

#### Position

Associate professor

#### Latest degree

Subspecialist

#### Other areas of specialty/work

Internal Medicine

#### Street address

3rd Floor, Central Building, University Street, Tabriz, Iran

#### City

Tabriz

#### Province

East Azarbaijan

#### Postal code

5157679746

#### Phone

+98 41 3329 6024

#### Email

halehmikaeili@gmail.com

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Tabriz University of Medical Sciences

#### Full name of responsible person

Haleh Mikaeili

#### Position

Associate professor

#### Latest degree

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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)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

Conscious consent form

**When the data will become available and for how long**

1 month after printing the results

**To whom data/document is available**

Researchers and treatment staff

**Under which criteria data/document could be used**

In order to cure

**From where data/document is obtainable**

Mikaeili haleh

**What processes are involved for a request to access data/document**

1 month

**Comments**