

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

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. Pao₂/fio₂<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 Pao₂/Fio₂<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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Khosro Adibkia

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

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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

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

Haleh Mikaeili

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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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