Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 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. 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

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

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 updating data

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

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 mounth

Comments