Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Effect of intratracheal Injection of Processed Autologous Serum Derived from Patients with covid-19 in oxygenation parameters and pulmonary Complications

Protocol summary

Study aim

To determine the effect of intratracheal injection of processed autologous serum derived from patients with COVID-19 in oxygenation parameters and pulmonary complications

Design

Randomised, superiority, parallel group, phase 2, single-center trial with blinded outcome assessment. Randomisation will be performed using block randomisation (n=4).

Settings and conduct

This study will be conducted in a 22-bed ICU in northwest of Iran. Intubated patients with COVID-19 under mechanical ventilation will be enrolled. The patients will receive all the standard treatments. Also, the blood sample of patients will undergo centrifugation with 5000/min for separating plasma and then will be incubated for 8 hours. Thereafter, the plasma will be injected intratracheally for patients. For patients in control group, normal saline serum in the same volume will be intratracheally administered. This procedure will be performed every 3 days and the maximum number of administration will be 3 times in both groups. Patients and their next of kin as well as the researcher who will assess the outcomes will be blind to the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: intubated COVID19 patients Exclusion criteria: transplantation history, malignancy, thoracic surgery, autoimmune disease and active bacterial infection

Intervention groups

In intervention group, the blood sample of patients will undergo centrifugation with 5000/min and then plasma will be incubated for 8 hours and injected intratracheally for patients. For control group, normal saline in the same volume will be intratracheally administered. This procedure will be performed every 3 days and the maximum number of administration will be 3 times in both groups.

Main outcome variables

Primary outcome: change in oxygenation Secondary outcomes: change in CO2; change in respiratory compliance; change in airway resistance

General information

Reason for update

Acronym

-

IRCT registration information

IRCT registration number: **IRCT20091012002582N21**
Registration date: **2020-05-18, 1399/02/29**
Registration timing: **retrospective**

Last update: **2020-05-18, 1399/02/29**
Update count: **0**

Registration date

2020-05-18, 1399/02/29

Registrant information

Name

Ata Mahmoodpoor

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 914 116 0888

Email address

mahmoodpoora@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-05, 1398/02/15

Expected recruitment end date

2019-08-06, 1398/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of intratracheal Injection of Processed Autologous Serum Derived from Patients with covid-19 in oxygenation parameters and pulmonary Complications

Public title

Effect of intrapulmonary injection of processed serum derived from covid-19 patients in reduction of pulmonary complications

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

intubated covid-19 patients

Exclusion criteria:

transplantation history malignancy thoracic surgery active bacterial infection autoimmune disease

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Initially, the blocks (n=4) with different arrangements of A and B will be defined. Considering the different probable arrangement of A and B, blocks will be numbered from 1 to 6. To enroll initial 4 patients into the study, one of the arrangements will be selected using the random digit table and the patients will be assigned into the A and B groups accordingly. For the next 4 patients, the arrangement pattern will be selected again and the patients will be assigned to the groups and this cycle will be repeated to achieve our intended sample size. Unpredictability of assignment and balancing the number of patients across the two groups during or at the end of the study are main advantages of this method. Notably, the patients will be assigned into the study based on the ICU date of admission and no body will be able to assign the patients to the specific group of interest.

Blinding (investigator's opinion)

Double blinded

Blinding description

The aim of double blinding is the avoidance of patients and researchers from being informed about the study intervention, so enrollment of patients in intervention and placebo groups will not be recognized. As the patients will be unconscious and under mechanical ventilation, they actually will not be aware of the group in which they are (intervention /placebo). The informed consent will be obtained from the patient's next of kin and they will thoroughly be informed about the study but they will be blind about the group in which their patient will be included. Also, the researcher who will assess the outcomes will not have any information about study enrollment and only primary investigator will know that. So, blinding will be performed for the researcher who will assess the study outcomes. As he/she will not be a member of treatment team and will be blinded to the study groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

Street address

General ICU, Imam Reza Hospital, Daneshkade Street

City

Tabriz

Province

East Azarbaijan

Postal code

5166614756

Approval date

2020-04-06, 1399/01/18

Ethics committee reference number

IR.TBZMED.REC.1399.014

Health conditions studied

1

Description of health condition studied

COVID-19

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified

Primary outcomes

1

Description
Oxygenation
Timepoint
During 10 days from intratracheal injection
Method of measurement
Arterial blood gas analysis

Secondary outcomes

1

Description
Change in CO2
Timepoint
During 10 days after intratracheal intubation
Method of measurement
Analysis of arterial blood gases

2

Description
Respiratory compliance
Timepoint
During 10 days after intratracheal intubation
Method of measurement
Ventilator

3

Description
Airway resistance
Timepoint
During 10 days after intratracheal intubation
Method of measurement
Ventilator

Intervention groups

1

Description
Intervention group: After taking blood samples and centrifugation with 5000/min the plasma will be separated and incubated for 8 hours and then this plasma will be injected intratracheally for the patient. This procedure will be performed every 3 days and the maximum number of administration will be 3 times.
Category
Treatment - Drugs

2

Description
Control group:in the same volume for the patients in control group normal saline is intratracheally will be injected.This procedure will be performed every 3 days and the maximum number of administration will be 3 times.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
ICU General, Imam Reza Hospital
Full name of responsible person
Ata Mahmoodpoor
Street address
Imam Reza Hospital, Daneshkade street
City
Tabriz
Province
East Azarbaijan
Postal code
5166614756
Phone
+98 41 3335 2073
Fax
+98 41 3335 2073
Email
amahmoodpoor@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Khosro Adibkia
Street address
Daneshkade street
City
Tabriz
Province
East Azarbaijan
Postal code
5165665931
Phone
+98 41 3335 7310
Email
adibkia@tbzmed.ac.ir
Grant name
non
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Leila Roshangar
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Histology
Street address
Faculty of Medicine, Daneshkade Street
City
Tabriz
Province
East Azarbaijan
Postal code
5166614766
Phone
+98 41 3334 2086
Fax
+98 41 3334 2086
Email
lroshangar@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Ata Mahmoodpoor
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
Street address
Imam Reza Hospital, Daneshkade street
City
Tabriz
Province
East Azarbaijan
Postal code
5166614756
Phone
+98 41 3335 2073
Email
amahmoodpoor@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Leila Roshangar
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Histology
Street address
Faculty of Medicine, Daneshkade Street
City
Tabriz
Province
East Azarbaijan
Postal code
5166614766
Phone
0098 41 3342086
Email
lroshangar@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Will be available if needed
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available