

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Effect of red blood cell exchange on hypoxemia in patients with severe COVID-19

Protocol summary

Study aim

The effect of red blood cell exchange on hypoxemia in COVID-19 patients

Design

A double-blind non-randomized phase 3 clinical trial with the control group

Settings and conduct

In patients with severe COVID-19, despite normal RBC counts, there is dysfunction in oxygen transfer due to the deformation and structure of RBCs. This study is performed as a non-randomized double-blind clinical trial to investigate the effect of RBC replacement on improving oxygenation and increasing the survival rate of patients with severe COVID-19 in Tehran.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Positive PCR test for COVID-19; ground glass opacity more than 50% in CT scan; RR>30; severe hypoxemia and O2 sat<80%; progressive hypoxemia and intubation in 24 h; presence of at least one risk factor for severe COVID-19 such as BMI>30, DM, pulmonary disease, immune deficiency. Exclusion criteria: death in 24 hours after admission; transferring to another hospital during treatment; pregnancy.

Intervention groups

The intervention group received standard treatment and RBC exchange. After determining the blood group and crossmatch, first, a single unit blood sampling equal to 250-300 cc is performed and a unit pack cell is transfused and this process is repeated up to 4 times. The control group received only standard treatment.

Main outcome variables

O2 saturation to more than 90% in the room; mortality rate

General information

Reason for update

Acronym

BEC

IRCT registration information

IRCT registration number: **IRCT20160316027081N2**

Registration date: **2021-05-13, 1400/02/23**

Registration timing: **registered_while_recruiting**

Last update: **2021-05-13, 1400/02/23**

Update count: **0**

Registration date

2021-05-13, 1400/02/23

Registrant information

Name

Saeed Soleiman-Meigooni

Name of organization / entity

AJA university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 4414 4939

Email address

s.s.meigooni@ajajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-21, 1400/02/01

Expected recruitment end date

2021-06-21, 1400/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of red blood cell exchange on hypoxemia in patients with severe COVID-19

Public title

Blood exchange in COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Positive PCR test for COVID-19 Ground glass opacity more than 50% in CT scan RR>30 Severe hypoxemia and O2 sat<80% Progressive hypoxemia and intubation in 24 h Presence of at least one risk factor for severe Covid-19 such as BMI>30, DM, Pulmonary disease, Immune deficiency

Exclusion criteria:

Death in 24 hours after admission Transferring to another hospital during treatment Pregnancy

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Investigator
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description

The researcher does not know which patients agree to have a red blood cell exchange. The person who analyzes the information and prepares the draft article.

Placebo

Not used

Assignment

Parallel

Other design features

This study is conducted for the first time in Iran.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Aja university of medical sciences

Street address

E'temadzadeh, Fatemi

City

Tehran

Province

Tehran

Postal code

1487784637

Approval date

2020-06-06, 1399/03/17

Ethics committee reference number

IR.AJAUMS.REC.1399.054

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

Pneumonia due to COVID-19

ICD-10 code

U07.1

ICD-10 code description

Pneumonia due to coronavirus disease 2019

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

Increasing O2 saturation more than 90%

Timepoint

The day 7 and 14

Method of measurement

Pulse oximetry in the room air

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

Mortality rate

Timepoint

The days 7, 14, 28

Method of measurement

Yes/ No

Intervention groups**1****Description**

Intervention group: after determining the blood group and crossmatch, first a single unit blood sampling equal to 250-300 cc is performed and a unit pack cell is transfused and this process is repeated up to 4 times. The whole process takes two days and the distance from one turn to the next is 12 hours.

Category

Treatment - Other

2**Description**

Control group: The control group receives only the standard treatment protocol of severe pneumonia of COVID-19 in accordance with the latest guideline of the Ministry of Health.

Category

Placebo

+98 21 8609 6350

Email

admin@ajaums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Artesh 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

Recruitment centers

1

Recruitment center

Name of recruitment center

Be'sat hospital

Full name of responsible person

Mohammad Aminianfar

Street address

Hejrat St, Basij Blvd, Afsarieh

City

Tehran

Province

Tehran

Postal code

1781997511

Phone

+98 21 3995 5555

Email

maminianfar@yahoo.com

2

Recruitment center

Name of recruitment center

Khanevadeh hospital

Full name of responsible person

Saeed Soleiman-Meigooni

Street address

Kaaj St, Shari'ati Blvd

City

Tehran

Province

Tehran

Postal code

1613917149

Phone

+98 21 7760 0500

Email

dr.saeed.meigooni@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

Mojtaba Yousefi Zoshk

Street address

E'temad Zadeh Av, Fatemi St

City

Tehran

Province

Tehran

Postal code

1411718701

Phone

Person responsible for general inquiries

Contact

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

Mohammad Aminianfar

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

Street address

Hejrat St, Basij Blvd, Afsarieh

City

Tehran

Province

Tehran

Postal code

1781997511

Phone

+98 21 3995 5555

Email

maminianfar@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

Mohammad Aminianfar

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Infectious diseases

Street address
Hejrat St, Basij Blvd, Afsarieh
City
Tehran
Province
Tehran
Postal code
1781997511
Phone
+98 21 3995 5555
Email
maminianfar@yahoo.com

+98 21 3995 5555
Email
maminianfar@yahoo.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

Specific participant data sets are to be shared

When the data will become available and for how long

Six months after publishing the data

To whom data/document is available

Deputy of research, Ministry of health

Under which criteria data/document could be used

After formal request

From where data/document is obtainable

AJA University of medical sciences, deputy of research

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

From Ministry of Health, Deputy of Research To AJA
University of Medical Sciences

Comments

Person responsible for updating data

Contact

Name of organization / entity
Artesh University of Medical Sciences
Full name of responsible person
Mohammad Aminianfar
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Infectious diseases
Street address
Hejrat St, Basij Blvd, Afsarieh
City
Tehran
Province
Tehran
Postal code
1781997511
Phone