Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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@ajaums.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

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

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1781997511

Phone
+98 21 3995 5555

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2

Recruitment center

Name of recruitment center
Khanevadeh hospital

Full name of responsible person
Saeed Soleiman-Meigooni

Street address
Kaaj St, Shari'ati Blvd

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1613917149

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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

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1411718701

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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

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

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Person responsible for scientific inquiries

Contact

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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
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