Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Evaluation of the Effect of Blood Transfusion on the Atrial Blood Oxygen Saturation percentage in COVID-19 patients

Protocol summary

Study aim

General Objectives: Determining the effect of blood transfusion on arterial blood oxygen saturation in patients with COVID-19

Design

A clinical trial with a control group, with parallel groups, one-way blind, randomized, on 80 patients (40 in the intervention group and 40 in the control group). Randomization will be done by the Blocked Randomization method. The intervention group includes patients with COVID19 who match the inclusion criteria and receive a unit of blood (Packed cell) in addition to receiving standard treatment. There are similar conditions in the control group, but patients do not receive blood.

Settings and conduct

Demographic information, admission and discharge day, patients' underlying diseases, symptoms at the time of arrival, laboratory findings of patients admitted to Bushehr Persian Gulf Martyrs Hospital are recorded in the checklist.

Participants/Inclusion and exclusion criteria

Inclusion: Confirmation of the COVID-19; hospitalization of the patient; more than 25% of pulmonary involvement in chest CT; SPO2 equal to or less than 94%; Hb less than 12 g/dl (female) or 13 (male); Absence of contraindications of blood transfusion; Satisfaction of the patient; exclusion: blood transfusion need for other reasons.

Intervention groups

In the intervention group, in addition to receiving the treatment process, patients receive a unit of packed cell blood. In the control group, patients will receive the standard treatment for COVID-19 as the intervention group (except for not receiving packed cells).

Main outcome variables

"Oxygen saturation percentage", "Hemoglobin", "Improvement of respiratory condition", "Number of hospitalization days"

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201003048904N1**
Registration date: **2020-10-11, 1399/07/20**
Registration timing: **registered_while_recruiting**

Last update: **2020-10-11, 1399/07/20**
Update count: **0**

Registration date

2020-10-11, 1399/07/20

Registrant information

Name

Farhad Abbasi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-11, 1399/07/20

Expected recruitment end date

2020-11-20, 1399/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the Effect of Blood Transfusion on the Atrial Blood Oxygen Saturation percentage in COVID-19 patients

Public title
Effect of Blood Transfusion in Covid-19
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Confirmation of Covid 19 The patient's clinical condition confirms the indication for hospitalization. Chest CT scan shows more than 25% of pulmonary involvement. SPO2 equal to or less than 94% on the day of admission Hemoglobin should be less than 12 g / dl (women) and less than 13 g / dl (men) on the day of admission. Absence of absolute or partial contraindications including history of allergies, anaphylaxis, history of thrombosis, pregnancy Satisfaction of the patient or his/her legal companions to participate in the study
Exclusion criteria:
Contraindications for receiving blood. The patient's unwillingness to receive blood. The need to receive blood as a treatment in the course of the disease for other reasons.
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Data analyser

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization will be done by the Blocked Randomization method. So that two groups T and C are considered as intervention and control groups. Allocating two groups equally in each block can be: TTCC, TCTC, TCCT, CCTT, CTCT, CTTC. Considering that there are 40 patients in each group, a total of 80 samples are needed, so from the above blocks, 20 blocks are randomly selected (placing all 6 types of blocks in a container and selecting it randomly and by placement). And they are written in a chain, for example: TTCC-CCTT-TTCC-CTTC-CTCT-TCTC-TCCT-TCCT-CTTC-TTCC... Group T patients will eventually be in the intervention group and group C patients will be in the control group, and it will be pre-determined in which group the patient will be placed.
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, the data analyzer is not aware of which group is the control group and which group is in the intervention group.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Bushehr University of Medical Sciences
Street address
Rishahr St. Bushehr University of Medical Sciences Campus
City
Bushehr
Province
Boushehr
Postal code
7518759577
Approval date
2020-09-16, 1399/06/26
Ethics committee reference number
IR.BPUMS.REC.1399.108

Health conditions studied

1

Description of health condition studied
Respiratory status of patients with Covid 19
ICD-10 code
U07.1
ICD-10 code description
COVID-19, virus identified

Primary outcomes

1

Description
Blood oxygen saturation
Timepoint
Admission day, The first day after the blood transfusion, The third day after the blood transfusion
Method of measurement
Pulse oximetry

Secondary outcomes

1

Description
Dyspnea status
Timepoint
Admission day, The first day after the blood transfusion, The third day after the blood transfusion

Method of measurement
Subjective: question from the patient. Objective: respiratory rate count in a minute

Intervention groups

1

Description
Intervention group: In this group, patients diagnosed with COVID19 who meet the inclusion criteria, in addition to receiving standard treatments according to the national protocol, receive a unit of blood (packed cell).
Category
Treatment - Other

2

Description
Control group: In this group, Covid 19 patients who meet the inclusion criteria receive standard treatments based on the national protocol and other therapeutic interventions during hospitalization, such as packed cell blood products or other interventions outside. Do not receive standard treatment.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shohadaye-khalije- Fars hospital
Full name of responsible person
Farhad Abbasi
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Taleghani Blvd.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Boushehr University of Medical Sciences
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Research@Bpums.Ac.Ir
Web page address
http://rs.bpums.ac.ir/fa/index.aspx
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Boushehr 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
Boushehr University of Medical Sciences
Full name of responsible person
Farhad Abbasi
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
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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
The main variables and outcomes studied will be published: Percentage of blood oxygen saturation, clinical symptoms, laboratory findings, and demographic variables.
When the data will become available and for how long
4 months after publishing the results
To whom data/document is available
Researchers member of formal research institutes and faculty members
Under which criteria data/document could be used
To integrate data with other studies
From where data/document is obtainable
Dr Farhad Abbasi: f_abbasi55@yahoo.com
What processes are involved for a request to access data/document
The objectives and scope of the draft research plan are reviewed and approved if they are consistent with the data.
Comments