

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 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)

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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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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Boushehr University of Medical Sciences

Full name of responsible person

gholamreza khamisipour

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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

Infectious diseases

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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**Person responsible for updating data****Contact****Name of organization / entity**

Boushehr University of Medical Sciences

Full name of responsible person

Negar Changizi

Position

Intern

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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