

# 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)

##### Phone

+98 77 3355 8990

##### Email address

fa.abbasi@bpums.ac.ir

##### 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

##### Street address

Taleghani Blvd.

##### City

Bushehr

##### Province

Boushehr

##### Postal code

7516654933

##### Phone

+98 77 3345 5381

##### Email

f\_abbasi55@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Boushehr University of Medical Sciences

##### Full name of responsible person

gholamreza khamisipour

##### Street address

Rishehr's Street

##### City

Bushehr

##### Province

Boushehr

##### Postal code

7518759577

##### Phone

+98 77 3345 0178

##### Email

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

Infectious diseases

##### Street address

No.15, Erfan 16 alley, Motahari St.

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f\_abbasi55@yahoo.com

## Person responsible for scientific 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

**Street address**

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**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

**Street address**

No. 4, Yas Building, 1\_1 Alley, East Qudusi St.

**City**

Shiraz

**Province**

Fars

**Postal code**

7184986145

**Phone**

+98 74 3232 6050

**Email**

negar.ch1993@gmail.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**

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**