Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jun 2026

Effect of hemoperfusion on short-term outcome of critically ill COVID-19 patients admitted to ICU

Protocol summary

Study aim
Effect of Hemoperfusion on short term survival of critical ill COVID-19 patients admitted to ICU

Design
Randomized, superiority, parallel group, phase 3, single-center trial with blinded outcome assessment. Randomization will be performed using qua-ternary blocking randomization.

Settings and conduct
Patients with Covid 19 admitted to the ICU of Imam Reza Hospital will be randomly assigned to the intervention and control groups. In the intervention group, in addition to routine treatments based on the national protocol, they will undergo hemoperfusion for 14-16 hours, and in the control group, only routine treatments of the intensive care unit based on the national protocol. It will be used to compare the effects of the effect of hemoperfusion on the short-term prognosis of patients in the intensive care unit of Covid_19 patients.Patients and their next of kin as well as the researcher who will assess the outcomes will be blind to the study.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients 18 to 75 years of age with Covid 19 Absence of active bleeding Absence of irreversible disease Existence of pulmonary involvement more than 50% Exclusion criteria: Pregnancy Dissatisfaction of the patient or the patient's companion

Intervention groups
Intervention group: This group will be performed under routine treatments in the intensive care unit according to the national protocol for Covid 19 patients plus 14-16 hours of hemoperfusion. Before and after each hemoperfusion session, disease severity factors will be checked and based on the symptoms and severity of the markers, if necessary, hemoperfusion will be repeated for up to 3 sessions. In the control group, only routine treatments of the intensive care unit will be provided according to the national protocol.

Main outcome variables
Duration of hospital stay in ICU, duration of mechanical ventilation, mortality

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20091012002582N22**
Registration date: **2020-08-08, 1399/05/18**
Registration timing: **prospective**

Last update: **2020-08-08, 1399/05/18**
Update count: **0**

Registration date
2020-08-08, 1399/05/18

Registrant information

Name
Ata Mahmoodpoor

Name of organization / entity
Tabriz University of Medical Sciences

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-08-22, 1399/06/01

Expected recruitment end date
2020-12-20, 1399/09/30

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of hemoperfusion on short-term outcome of critically ill COVID-19 patients admitted to ICU

Public title

Effect of hemoperfusion on short term outcome of critical ill COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients 18 to 75 years of age with Covid 19 Absence of active bleeding Absence of irreversible disease Existence of pulmonary involvement more than 50%

Exclusion criteria:

Pregnancy Dissatisfaction of the patient or the patient's companion

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **160**

Randomization (investigator's opinion)

Randomized

Randomization description

Initially, the blocks (n=4) with different arrangements of A and B will be defined. Considering the different probable arrangement of A and B, blocks will be numbered from 1 to 6. To enroll initial 4 patients into the study, one of the arrangements will be selected using the random digit table and the patients will be assigned into the A and B groups accordingly. For the next 4 patients, the arrangement pattern will be selected again and the patients will be assigned to the groups and this cycle will be repeated to achieve our intended sample size. Unpredictability of assignment and balancing the number of patients across the two groups during or at the end of the study are main advantages of this method. Notably, the patients will be assigned into the study based on the ICU date of admission and no body will be able to assign the patients to the specific group of interest.

Blinding (investigator's opinion)

Double blinded

Blinding description

The aim of double blinding is the avoidance of patients and researchers from being informed about the study intervention, so enrollment of patients in intervention and placebo groups will not be recognized. The informed consent will be obtained from the patient's next of kin and they will thoroughly be informed about the study but they will be blind about the group in which their patient will be included. Also, the researcher who will assess the outcomes will not have any information about study enrollment and only primary investigator will know that. So, blinding will be performed for the researcher who will assess the study outcomes. As he/she will not be a member of treatment team and will be blinded to the study groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Committee of Tabriz University of Medical Sciences

Street address

Vice chancellor for research, Golgasht Street

City

Tabriz

Province

East Azarbaijan

Postal code

5183915881

Approval date

2020-08-02, 1399/05/12

Ethics committee reference number

IR.TBZMED.REC.1399.493

Health conditions studied

1

Description of health condition studied

COVID-19

ICD-10 code

U07.1

ICD-10 code description

COVID-19

Primary outcomes

1

Description

Duration of mechanical ventilation.

Timepoint

From the time the patient enters the ICU until discharge from this ward.

Method of measurement

Number of days the patient is under mechanical ventilation based on patients recorded information

Secondary outcomes

1

Description
Mortality
Timepoint
From the beginning of the interventions to 28 days after the end of the interventions
Method of measurement
Mortality counting based on patients recorded information

2

Description
ICU length of stay
Timepoint
From the time of the patient's arrival until the discharge of ICU
Method of measurement
According to the number of days the patient was hospitalized in the ICU

Intervention groups

1

Description
Control group:In the control group, patients will receive all standard treatments as follows: In case of no mechanical ventilation, use of NIV or face mask in case of mechanical ventilation, Lung protective strategy / low tidal volume ventilation with a target volume of 6 ml / kg of ideal body weight with the aim of plateau pressure below 30 and Driving pressure below 50 and maintaining oxygenation and carbon dioxide pressure will be desirable. Patients will receive antiviral therapy and corticosteroids. Patients with a goal of 25 kcal per kg of body weight will be fed daily and laterally, and if this is not possible, this energy will be provided parenterally. Blood sugar control in the range 140-180 will be performed for all patients.PPI treatment to prevent ulcer stress and anticoagulant therapy with prophylactic dose will be performed for all patients. Complementary medications will be prescribed as needed. All patients will undergo the ABCDE protocol for monitoring delirium treatment.
Category
Treatment - Devices

2

Description
Intervention group:In the hemoperfusion group, in addition to the treatments in the control group, patients will be hemoperfused for 16-14 hours with a cytosorbe filter of 300 and BFR: 250-300 ml / min and heparin at a dose of 10-15 IV / Kg / h. PTT Patients will be performed every 4 hours to maintain PTT in the treatment area. Before and after each hemoperfusion session, the disease severity factors will be checked and based on the symptoms and severity of the markers, if necessary, hemoperfusion will be repeated for up to 3 sessions.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
General ICU, Imam Reza Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
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Full name of responsible person
Mojtaba Mohammadzadeh
Position
subspeciality resident
Latest degree
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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
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
All potential data can be shared after making peoples unrecognizable.
When the data will become available and for how long
Starting 6 months after publication .
To whom data/document is available
Documents will be available for people working in academic institutions and also people working in businesses.
Under which criteria data/document could be used

There will be no specific limitations to the utilization of the data

From where data/document is obtainable

Dr .Ata Mahmoodpoor, Department of Anesthesiology, Faculty of Medicine, Golgasht Street, Tabriz East Azarbaijan Islamic Republic of Iran ,Phone+98 413 3341994, Fax+98 41 33341994 , amahmoodpoor@yahoo.com

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

Applicants will access the data from the present study by sending an email to the responsible author for a maximum of one week.

Comments