

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

Evaluation of Hemoperfusion effect in treatment of patients with COVID-19 hospitalized in intensive care unit, Randomized clinical trial

Protocol summary

Study aim

The effect of hemoperfusion in the treatment of patients with Covid-19 disease admitted to the intensive care unit

Design

A randomized, single-blinded clinical trial with a control group and parallel design of 20 patients

Settings and conduct

This study is a clinical trial in Razi Hospital, Rasht, on critically ill patients with COVID-19 admitted to the ICU. Patients will enter the study after obtaining the informed consent and get randomly in one of the two groups. The Cartridge used for hemoperfusion is Jafron HA 330, number of sessions: 3, pump speed of the device: 250 to 300, duration of each session: 4 hours, interval between sessions: 8 to 12 hours. For 14 days, patients in both groups will be monitored daily for vital signs, electrolytes, liver and kidney tests, blood cells, coagulation and inflammatory factors, chest radiographs and possible gastrointestinal complications. Finally, the two groups are compared in terms of treatment effectiveness and possible side effects. Participants and physicians in charge will not be blind, but radiologists, researchers evaluating the research and statistics will be blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients admitted to the ICU with a clinical diagnosis of Covid-19 with a respiratory rate \geq 30, heart rate \geq 125, oxygen saturation \leq 90%, uncontrollable fevers such as $T > 39$ C, increased inflammatory factors, severe hemodynamic disturbance, involvement of more than two vital organs
Exclusion criteria: Thrombocytopenia (Plt \leq 20000), pregnancy, acute crisis due to sickle cell anemia, resin sensitivity.

Intervention groups

The first group will receive the standard COVID-19 treatment based on the national protocol. The second group will receive the standard COVID-19 treatment along with 3 sessions of hemoperfusion according to the

protocol provided by the Ministry of Health.

Main outcome variables

Improving the patient's clinical condition

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110425006280N12**

Registration date: **2021-08-14, 1400/05/23**

Registration timing: **prospective**

Last update: **2021-08-14, 1400/05/23**

Update count: **0**

Registration date

2021-08-14, 1400/05/23

Registrant information

Name

Mohammad Haghghi

Name of organization / entity

Guilan University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-23, 1400/06/01

Expected recruitment end date

2022-03-20, 1400/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Hemoperfusion effect in treatment of patients with COVID-19 hospitalized in intensive care unit, Randomized clinical trial

Public title

Hemoperfusion effect in treatment of patients with COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with a clinical diagnosis of Covid-19 including respiratory distress with a rate of more than 30 per minute and heart rate more than 125 beats per minute and shortness of breath and oxygen saturation less than 90%, despite receiving oxygen with a positive PCR test and Radiographs in CT SCANNING or Chest X Ray, admitted to the intensive care unit. Uncontrollable fevers like T> 39 C. An laboratory evidence of increased inflammatory factors Patients 12 years and older Evidence of severe hemodynamic disturbance using moderate doses of norepinephrine or using a second dose of vasopressor Involvement of more than two vital organs (lungs, kidneys, liver, and heart)

Exclusion criteria:

Thrombocytopenia (Plt ≤20,000) Pregnancy Acute crisis due to sickle cell anemia Evidence of resin sensitivity

Age

From 12 years old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: 20

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, patients will enter each of the two treatment groups randomly using a 1: 1 block randomization method. Twenty patients with a diagnosis of Covid 19 will be divided into 2 groups of 10 intervention and control. The hemoperfusion group is called A and the control group is called B. Random blocking will be done in such a way that the research units are assigned numbers 1-20, respectively. Then a table with 6 rows called blocks and each block will have 4 parts and each part will be named with A and B, will be considered. In the next step, the numbers will be placed in each house in order. After all the numbers are placed in the blocks, the people who had the number in house A will receive the hemoperfusion method and the people

who had the number in house B will be considered the control group. The website <https://www.sealedenvelope.com> is used for randomization. For hiding, the Allocation concealment method will be used. So that before the individual is assigned, the assigned group is not specified. In this method, using the same sealed envelopes, with a random sequence in which each of the random sequences created on this card is recorded and the cards inside the envelopes will be placed in order. In order to maintain a random sequence, the envelopes are numbered in the same way on the outer surface. At the beginning of the registration of eligible patients, one of the envelopes will be opened and the patient will be a candidate for hemoperfusion or control group.

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants and health care providers responsible for patients' health will not go blind and are informed about the therapy groups. Radiologists, researchers evaluating the research and statistical expertise will be blind. Sequentially numbered opaque, sealed envelopes: Envelopes method is used to hide random allocation.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethical Committee of Guilan University of Medical Sciences

Street address

Namjoo Avenue, Deputy department OF Guilan University of Medical Sciences

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Province

Guilan

Postal code

4193713189

Approval date

2021-06-30, 1400/04/09

Ethics committee reference number

IR.GUMS.REC.1400.136

Health conditions studied**1****Description of health condition studied**

The effect of Hemoperfusion in the treatment of covid-19

disease
ICD-10 code
U07.1
ICD-10 code description
COVID-19, virus identified

Primary outcomes

1

Description

Improving the patient's clinical condition

Timepoint

Daily

Method of measurement

Evaluation of the presence of Respiratory distress, marked improvement in patients respiration rate, improvement in arterial blood gas condition and self-expression, improvement in patient's heart rate and improvement in patient's inflammatory tests 2-3 days after home perfusion. Inflammatory tests include D.DIMER, IL-6 LDH, FERRITIN, FIBRINOGEN, CRP

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group includes 10 patients who enter the study after obtaining the informed consent of the patient or her companion and receive the standard COVID-19 treatment regimen along with 3 sessions of hemoperfusion according to the protocol provided by the Ministry of Health. The standard treatment includes the antiviral drug remedicivier and interferon ReciGen and the use of corticosteroids and dexamethasone and other complementary measures such as anticoagulants and antacids and sedatives. The use of a homeperfusion device can be alone or in combination. In the combined use of hemoperfusion, the cartridge is placed before the hemodialysis filter or hemofilter. Cartridge used: Jafron HA 330 - Number of sessions: 3 - Device: Hemoperfusion - Pump speed of the device: 250 to 300 - Duration of each session: 4 hours - Interval between sessions: 8 to 12 hours - Low-dose of heparin will be infused. It is prescribed at a dose of 10 to 15 units per kilogram per hour to avoid cartridge damage. If CVVH mode is established and added from CRRT, the dose of heparin will increase to 15-20 units per kilogram per hour. For hemoperfusion, you can use a special device for hemoperfusion or if you do not have access to a hemoperfusion device, you can use a hemodialysis machine, because to perform hemoperfusion, you need vascular access (shaldon) and a pump that removes blood from the body and returns it to the body. And a hemodialysis machine makes this possible. Patients are monitored daily for vital signs, electrolytes, blood sugar, liver tests, kidney tests, blood cells, coagulation factors,

LDH, inflammatory factors, and chest radiographs. To compare the effectiveness and speed of recovery between the two intervention and control groups, changes in clinical symptoms (fever, oxygen saturation, alertness, blood pressure, heart rate, respiratory distress, etc.) and paraclinical changes (changes in chest imaging, changes in lymphocyte count). LDH, changes in CRP, ESR, D.DIMER, serum creatinine, ALT, AST, bilirubin and alkaline phosphatase, interleukin 6 and ferritin) are checked twice a week.

Category

Treatment - Devices

2

Description

Control group includes 10 patients who enter the study after obtaining the informed consent of the patient or her companion and receive the standard COVID-19 treatment regimen. The standard treatment includes the antiviral drug remedicivier and interferon ReciGen and the use of corticosteroids and dexamethasone and other complementary measures such as anticoagulants and antacids and sedatives. Patients are monitored daily for vital signs, electrolytes, blood sugar, liver tests, kidney tests, blood cells, coagulation factors, LDH, inflammatory factors, and chest radiographs. To compare the effectiveness and speed of recovery between the two intervention and control groups, changes in clinical symptoms (fever, oxygen saturation, alertness, blood pressure, heart rate, respiratory distress, etc.) and paraclinical changes (changes in chest imaging, changes in lymphocyte count). LDH, changes in CRP, ESR, D.DIMER, serum creatinine, ALT, AST, bilirubin and alkaline phosphatase, interleukin 6 and ferritin) are checked twice a week.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Vice President of Research Guilan 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**

Guilan University of Medical Sciences

Full name of responsible person

Mohammad Haghighi

Position

Professor of Critical Care Medicine

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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