Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 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≥ 30,heart rate≥125,oxygen saturation≤90% ,uncontrollable fevers such asT>39 C,increased inflammatory factors, severe hemodynamic disturbance,involvement of more than two vital organs Exclusion criteria:Thrombocytopenia (Plt ≤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

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Guilan University of Medical Sciences

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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 SCANING 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 Comeetee of Guilan University of Medical Sciences
Street address
Namjoo Avenue, Deputy department OF Guilan University of Medical Sciences
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Province
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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

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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
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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