Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

To evaluate the effectiveness of hemoperfusion in patients with severe coronavirus disease 2019 (COVID-19)

Protocol summary

Study aim

Considering the role of inflammatory cytokines in COVID-19 disease and its severity, this study was designed to evaluate the effectiveness of hemoperfusion that can remove inflammatory cytokines from the blood.

Design

This clinical trial will be conducted with one intervention group, with no control group and no blindness on 10 hospitalized patients with severe forms of COVID-19.

Settings and conduct

This clinical trial will be conducted with one intervention group, with no control group and no blindness on 10 hospitalized patients admitted in Ayatollah Rouhani Hospital in Babol, Mazandaran with severe forms of COVID-19 who no improvement was observed in their disease course despite receiving different treatments.

Participants/Inclusion and exclusion criteria

The participants are hospitalized patients with severe forms of COVID-19. Inclusion Criteria: Patients with diagnosis of COVID-19 based on the clinical manifestations, lung CT-scan, testing of pharyngeal sample using real-time polymerase chain reaction and the physician´s diagnosis; Patients who have PaO2 less than 60; Patients who have PaO2/FiO2 less than 200; Patients who have PaCo2 more than 50; SpO2 less than 88%, and no improvement has been achieved despite 48 hours of non-invasive respiratory therapy. Exclusion Criteria: Plasma platelets count less than 30000 per microliter; Multiple organ failure

Intervention groups

Intervention Group: Patients undergo extracorporeal blood purification on three sessions. Each session conducts in six hours per day, using hemoperfusion filters. The second course of hemoperfusion is performed 12-24 hours after the first and the third session 24 hours after the second time. Control Group: Since the patients with severe coronavirus disease (COVID-19) have been enrolled in the study, no control group is considered.

Main outcome variables

Improving the general condition of the patient

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150704023055N2**
Registration date: **2020-04-03, 1399/01/15**
Registration timing: **retrospective**

Last update: **2020-04-03, 1399/01/15**
Update count: **0**

Registration date

2020-04-03, 1399/01/15

Registrant information

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Simin Mouodi
Name of organization / entity
Babol University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-24, 1399/01/05

Expected recruitment end date

2020-04-03, 1399/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
To evaluate the effectiveness of hemoperfusion in patients with severe coronavirus disease 2019 (COVID-19)

Public title
Hemoperfusion in patients with COVID-19

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with diagnosis of COVID-19 based on the clinical manifestations, lung CT-scan, testing of pharyngeal sample using real-time polymerase chain reaction and the physician´s diagnosis Patients who have partial pressure of oxygen in alveoli (PaO2) less than 60, even after different methods of oxygen-therapy Patients who have partial pressure of oxygen in alveoli to the fraction of inspired oxygen (PaO2/FiO2) less than 200 Patients who have partial pressure of carbon dioxide in alveoli (PaCo2) more than 50; PH less than 7.35; peripheral capillary oxygen saturation (SpO2) less than 88%; and no improvement has been achieved despite 48 hours of non-invasive respiratory therapy

Exclusion criteria:
Plasma platelet count less than 30000 per microliter Multiple organ dysfunction

Age
From **18 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **10**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Babol University of Medical Sciences

Street address
Ganjafrooz Avenue, Babol

City
Babol

Province
Mazandaran

Postal code
4136747176

Approval date
2020-03-24, 1399/01/05

Ethics committee reference number
IR.MUBABOL.HRI.REC.1399.038

Health conditions studied

1

Description of health condition studied
COVID-19

ICD-10 code
U07.1

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

2

Description of health condition studied
COVID-19

ICD-10 code
U07.2

ICD-10 code description
U07.2: COVID-19, virus not identified

Primary outcomes

1

Description
Improving the general condition of the patient

Timepoint
Before intervention and one week after the third session of hemoperfusion

Method of measurement
No need to receive any intensive respiratory care in the patient

Secondary outcomes

1

Description
Serum level of interleukin- 6

Timepoint
Before the first and after the third session of hemoperfusion

Method of measurement
To test the blood sample

Intervention groups

1

Description
Intervention group: Patients undergo extracorporeal blood purification on three sessions. Each session conducts in six hours per day, using hemoperfusion filters (HA280 and HA230) manufactured by the Jafron Company, China. The second course of hemoperfusion is performed 12-24 hours after the first and the third session 24 hours after the second time.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Rouhani Hospital
Full name of responsible person
Masoumeh Asgharpour
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Babol University of Medical Sciences
Full name of responsible person
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Web page address
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Grant name
Grant code / Reference number
724132940
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Babol 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
Babol University of Medical Sciences
Full name of responsible person
Masoumeh Asgharpour
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
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Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Information on the clinical features of patients, without mentioning their individual characteristics, will be published through the final report of the study.

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

No - There is not 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

No - There is not a plan to make this available

Title and more details about the data/document

Information on the clinical features of patients, without mentioning their individual characteristics, will be published through the final report of the study.

When the data will become available and for how long

Following the release of the final project report, after receiving an email from academic researchers, the questions will be answered within a maximum of two weeks.

To whom data/document is available

Academic researches

Under which criteria data/document could be used

After receiving an email from academic researchers

From where data/document is obtainable

Dr Masoumeh Asgharpour

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

The questions will be answered within a maximum of two weeks after receiving the email.

Comments