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

Hemoperfusion in patients with COVID-19

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**
- Not blinded

**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
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Sponsors / Funding sources

1

Sponsor
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Research in clinical sciences

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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 researchers

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