

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 2026

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

#### Protocol summary

Improving the general condition of the patient

#### 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 PaO<sub>2</sub> less than 60; Patients who have PaO<sub>2</sub>/FiO<sub>2</sub> less than 200; Patients who have PaCo<sub>2</sub> more than 50; SpO<sub>2</sub> 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

#### 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

##### Name

Simin Mouodi

##### Name of organization / entity

Babol University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3219 0624

##### Email address

s.mouodi@mubabol.ac.ir

##### 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 (PaO<sub>2</sub>) 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 (PaO<sub>2</sub>/FiO<sub>2</sub>) less than 200 Patients who have partial pressure of carbon dioxide in alveoli (PaCo<sub>2</sub>) more than 50; PH less than 7.35; peripheral capillary oxygen saturation (SpO<sub>2</sub>) 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

#### Street address

Ayatollah Rouhani Hospital, Ganjafrooz Avenue, Babol, Mazandaran, Iran

#### City

Babol

#### Province

Mazandaran

#### Postal code

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#### Phone

+98 11 3223 8260

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#### Email

masi9932002@yahoo.com

#### Web page address

http://rohani.mubabol.ac.ir

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Babol University of Medical Sciences

#### Full name of responsible person

Reza Ghadimi

#### Street address

Ganjafrooz Avenue, Babol

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#### Email

rezaghadimi@yahoo.com

#### Web page address

https://research.mubabol.ac.ir

#### 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

Nephrology

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Ganjafrooz avenue, Babol

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#### Province

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## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

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#### Full name of responsible person

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Babol University of Medical Sciences  
**Full name of responsible person**  
Simin Mouodi  
**Position**  
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**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Research in clinical sciences  
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**Province**  
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**Postal code**  
4136747176  
**Phone**  
+98 11 3219 4720  
**Fax**

+98 11 3219 7667

**Email**  
dr.mouodi@gmail.com  
**Web page address**

## 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