

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

23 Feb 2026

### Comparison of therapeutic effects of hemoperfusion in intubated and non-intubated patients with respiratory failure caused by the COVID-19

#### Protocol summary

##### Study aim

Determination of therapeutic effects of hemoperfusion in intubated and non-intubated patients with respiratory failure caused by the COVID-19

##### Design

Clinical trial with one intervention group, with no control group and no blindness on 40 hospitalized patients with severe forms of COVID-19.

##### Settings and conduct

This nonrandomized with no blindness clinical trial will be performed in Loghman Hakim Hospital on patients after obtaining permission from the ethics committee on patients with respiratory failure caused by the COVID-19, who are on antiviral medication according to national protocol. Patients will be divided into two groups; intubated and non-intubated. Intervention group will be treated with hemoperfusion. Laboratory and clinical finding will be evaluated. The data will be analyzed by SPSS software.

##### 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 PCR and the physician's diagnosis; Patients who have SpO<sub>2</sub> less than 85%, and no improvement has been achieved despite 48 hours of standard treatment. Exclusion Criteria: Plasma platelets count less than 30000 per microliter; Multiple organ failure

##### Intervention groups

Intervention group: 40 eligible patients with severe COVID-19 in a 1:1 ratio: (20 intubated and 20 non-Intubated)hemoperfusion + Standard of care treatment

##### Main outcome variables

O<sub>2</sub> Saturation CRP Ferritin Vasopressor need Length of hospital stay Mortality

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200608047686N2**

Registration date: **2020-11-19, 1399/08/29**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-11-19, 1399/08/29**

Update count: **0**

##### Registration date

2020-11-19, 1399/08/29

##### Registrant information

##### Name

Muhanna Kazempour

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 5541 7243

##### Email address

muhannakazempour@sbmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-10-17, 1399/07/26

##### Expected recruitment end date

2021-01-17, 1399/10/28

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of therapeutic effects of hemoperfusion in intubated and non-intubated patients with respiratory failure caused by the COVID-19

**Public title**

The role of hemoperfusion in COVID-19

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

Hospitalized patients with respiratory failure caused by the COVID-19

**Exclusion criteria:****Age**

From **18 years** old

**Gender**

Both

**Phase**

2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **40**

**Randomization (investigator's opinion)**

Not randomized

**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 Shahid beheshti University of Medical Sciences

**Street address**

Yaman St, Velenjak, Shahid Chamran Highway

**City**

Tehran

**Province**

Tehran

**Postal code**

19857-17443

**Approval date**

2020-10-13, 1399/07/22

**Ethics committee reference number**

IR.SBMU.RETECH.REC.1399.582

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

COVID-19

**ICD-10 code**

U07.1

**ICD-10 code description**

COVID-19

**Primary outcomes****1****Description**

O2 Saturation

**Timepoint**

Before and after the sessions of hemoperfusion

**Method of measurement**

Pulse Oximetry

**2****Description**

CRP

**Timepoint**

Before and after the sessions of hemoperfusion

**Method of measurement**

Blood level

**3****Description**

Ferritin

**Timepoint**

Before and after the sessions of hemoperfusion

**Method of measurement**

Blood level

**4****Description**

Vasopressor need

**Timepoint**

Before and after the sessions of hemoperfusion

**Method of measurement**

Observation

**Secondary outcomes****1****Description**

Lenght of hospitat stay

**Timepoint**

Daily up to discharge

**Method of measurement**

Days of hospitalization

## 2

### Description

Mortality

### Timepoint

Daily up to 28 days

### Method of measurement

Observation

## Intervention groups

### 1

#### Description

Intervention group: 40 eligible patients with severe COVID-19 in a 1:1 ratio: (20 intubated and 20 non-intubated)hemoperfusion + Standard of care treatment

#### Category

Treatment - Devices

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Loghman Hakim Hospital

##### Full name of responsible person

Muhanna Kazempour

##### Street address

Loghman Hakim Hospital, Kamali Street, South Karegar Avenue

##### City

Tehran

##### Province

Tehran

##### Postal code

1333625445

##### Phone

+98 21 5541 7243

##### Email

edulhmc@sbmu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Afshin Zarghi

##### Street address

Yaman St, Velenjak St, Shahid Chamran Highway

##### City

Tehran

##### Province

Tehran

##### Postal code

1985717443

##### Phone

+98 21 2243 9770

#### Email

info@sbmu.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Muhanna Kazempour

##### Position

Associate professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Internal Medicine

##### Street address

Loghman Hakim Hospital, Kamali Ave, South Kargar St

##### City

Tehran

##### Province

Tehran

##### Postal code

1333625445

##### Phone

+98 21 5541 9005

##### Email

muhannakazempour@gmail.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Muhanna Kazempour

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is 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**

Yes - There is 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

**Title and more details about the data/document**

At the time of publication

**When the data will become available and for how long**

At the time of publication

**To whom data/document is available**

Public

**Under which criteria data/document could be used**

They will be publically available.

**From where data/document is obtainable**

The study protocol, statistical analytic plan will be shared  
as supplementary material at the time of publication of  
results

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

The study protocol, statistical analytic plan will be shared  
as supplementary material at the time of publication of  
results

**Comments**