

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Treatment of COVID-19-induced cytokine storm with filter hemoperfusion HA330

#### Protocol summary

##### Study aim

To determine the effectiveness of hemoperfusion to remove cytokines-induced by COVID-19 in the blood

##### Design

A clinical trial, with one intervention group, with no control group, without blindness, ten patients with severe forms of COVID-19, Phase 2.

##### Settings and conduct

This study will be performed in Imam Reza Hospital, Tabriz, Iran. This clinical trial will be conducted on one intervention group, with no control group and no blindness on 10 hospitalized patients admitted with severe forms of COVID-19 and before intubation. CT scan of lungs, biochemical tests, hospitalization period, need to intubation and mortality rate will be assessed in this group.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with severe cytokine storm and respiratory symptoms (ARDS); Patients with a respiratory rate of more than 30; PaO<sub>2</sub>/FiO<sub>2</sub> less than 300 mm Hg; Age 18-65 year; immediate need for intubation. Exclusion criteria: advanced multi-organ failure; coagulation abnormality; other viral infection and bacterial sepsis; plasma platelets count less than 30000 per microliter.

##### Intervention groups

Intervention group: Patients undergo dialysis on 2 sessions 4 hours with hemoperfusion HA330 filter. The second course of hemoperfusion is performed 18-24 hours after the first session.

##### Main outcome variables

The change of pneumonia severity on CT scanning; ARDS symptoms; mortality rate; hospitalization period

#### General information

##### Reason for update

##### Acronym

HemoCov

#### IRCT registration information

IRCT registration number: **IRCT20200317046797N5**

Registration date: **2020-04-19, 1399/01/31**

Registration timing: **prospective**

Last update: **2020-04-19, 1399/01/31**

Update count: **0**

#### Registration date

2020-04-19, 1399/01/31

#### Registrant information

##### Name

Sepideh Zununi Vahed

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3336 9331

##### Email address

sepide.zununi@gmail.com

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2020-04-20, 1399/02/01

#### Expected recruitment end date

2020-07-22, 1399/05/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Treatment of COVID-19-induced cytokine storm with filter hemoperfusion HA330

#### Public title

Treatment of COVID-19-induced cytokine storm by hemoperfusion

### **Purpose**

Treatment

### **Inclusion/Exclusion criteria**

#### **Inclusion criteria:**

Positive PCR for COVID-19 PaO<sub>2</sub>/FiO<sub>2</sub> less than 200 mmHg More than 50% involvement of pulmonary fields in CT scan Respiratory rate more than 30/minute Resting O<sub>2</sub> saturation less than 90%

#### **Exclusion criteria:**

Coagulation abnormality Plasma platelets count <30000/μL Other viral infection and bacterial sepsis Advanced multi-organ failure

### **Age**

From **18 years** old to **65 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**

Tabriz University of Medical Sciences

##### **Street address**

3th floor of Tabriz University of Medical Sciences  
Central Building, Golgasht Street, Tabriz

##### **City**

Tabriz

##### **Province**

East Azarbaijan

##### **Postal code**

5166614766

#### **Approval date**

2020-04-18, 1399/01/30

#### **Ethics committee reference number**

IR.TBZMED.REC.1399.024

## **Health conditions studied**

### 1

#### **Description of health condition studied**

COVID-19

#### **ICD-10 code**

U07.1

#### **ICD-10 code description**

COVID-19, virus identified

### 2

#### **Description of health condition studied**

COVID-19-induced pneumonia

#### **ICD-10 code**

J12.81

#### **ICD-10 code description**

Pneumonia due to SARS-associated coronavirus

## **Primary outcomes**

### 1

#### **Description**

The general condition of the patient

#### **Timepoint**

Before intervention and 1 day after final intervention

#### **Method of measurement**

Lung CT scan; No need to receive any intensive respiratory care in the patient

### 2

#### **Description**

Mortality rate

#### **Timepoint**

At baseline and discharge time or patient death

#### **Method of measurement**

Observation

### 3

#### **Description**

Need for intubation

#### **Timepoint**

Period of hospitalization

#### **Method of measurement**

Observation or reading of hospitalized documents

### 4

#### **Description**

Period of hospitalization

#### **Timepoint**

At baseline and discharge time

#### **Method of measurement**

Number of hospitalized days

## **Secondary outcomes**

empty

## Intervention groups

1

### Description

Intervention group: Patients undergo hemodialysis on 2 sessions, each session will be conducted in 4 hours using hemoperfusion HA330 filter (JAFRON BIOMEDICAL.CO.LTD, China). The second round will be performed 18-24 hours after the first time. Protocol: a blood flow 150cc/minute, Heparin 10-12 unit per kg per hour.

### Category

Treatment - Devices

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Imamreza Hospita of Tabriz

#### Full name of responsible person

Dr Bahram Niknafs

#### Street address

Imamreza Hospital, Daneshgah Street

#### City

Tabriz

#### Province

East Azarbaijan

#### Postal code

5166614756

#### Phone

+98 41 3334 7054

#### Email

bahramniknafs@gmail.com

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Tabriz University of Medical Sciences

#### Full name of responsible person

Dr Mohammad Samiei

#### Street address

3th floor of Tabriz University of Medical Sciences  
Central Building, Golgasht Street, Tabriz

#### City

Tabriz

#### Province

East Azarbaijan

#### Postal code

5166614766

#### Phone

+98 41 3335 7310

#### Email

Samiei.moh@gmail.com

### Grant name

### Grant code / Reference number

### Is the source of funding the same sponsor

### organization/entity?

Yes

### Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

#### Full name of responsible person

Ali Taghizadieh

#### Position

Associate professor

#### Latest degree

Subspecialist

#### Other areas of specialty/work

Internal Medicine

#### Street address

Gholgasht Street, Tabriz University of Medical  
Sciences

#### City

Tabriz

#### Province

East Azarbaijan

#### Postal code

5166614766

#### Phone

+98 41 1335 2078

#### Email

alitaghizadieh@yahoo.com

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Tabriz University of Medical Sciences

#### Full name of responsible person

Mohammadreza Ardalan

#### Position

Professor

#### Latest degree

Subspecialist

#### Other areas of specialty/work

Internal Medicine

#### Street address

Tabriz University of Medical Sciences, Golgasht  
Street

#### City

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166614766

**Phone**

+98 41 3336 9331

**Email**

ardalan34@yahoo.com

**Postal code**

5166614766

**Phone**

+98 41 3336 9331

**Email**

sepide.zununi@gmail.com

**Person responsible for updating data****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Sepideh Zununi Vahed

**Position**

Assistant Prof.

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Biotechnology

**Street address**

Tabriz University of Medical Sciences, Gholghasht

Street

**City**

Tabriz

**Province**

East Azarbaijan

**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