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; PaO2/FiO2 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 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
- PaO2/FiO2 less than 200 mmHg
- More than 50% involvement of pulmonary fields in CT scan
- Respiratory rate more than 30/minute
- Resting O2 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
3rd floor of Tabriz University of Medical Sciences Central Building, Golgasht Street, Tabriz
City
Tabriz
Province
East Azerbaijan
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 Hospital of Tabriz
Full name of responsible person
Dr Bahram Niknafs
Street address
Imamreza Hospital, Daneshgah Street
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5166614756
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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
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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
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  ardalan34@yahoo.com

**Person responsible for updating data**

**Contact**

- **Name of organization / entity**
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- **Full name of responsible person**
  Sepideh Zununi Vahed

- **Position**
  Assistant Prof.

- **Latest degree**
  Ph.D.

- **Other areas of specialty/work**
  Medical Biotechnology

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**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