Clinical Trial Protocol
Iranian Registry of Clinical Trials
20 Oct 2020

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 date
2020-04-19, 1399/01/31

Registrant information
Name
Sepideh Zununi Vahed

Name of organization / entity
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Iran (Islamic Republic of)

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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 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**
   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

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Sponsors / Funding sources

1

Sponsor

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Person responsible for general inquiries

Contact

Name of organization / entity
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Position
Associate professor

Latest degree
Subspecialist

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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