

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; 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

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 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/ μ L 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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Imamreza Hospital, Daneshgah Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

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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

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

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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

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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