Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 COVOID-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 SpO2 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
O2 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)

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+98 21 5541 7243

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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
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Loghman Hakim Hospital, Kamali Street, South Karegar Avenue
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
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Yaman St, Velenjak St, Shahid Chamran Highway
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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
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
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Person responsible for updating data

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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