Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jun 2026

Evaluation of the effectiveness of plasmapheresis treatment in comparison with standard treatment in improving the symptoms of high-risk patients

Protocol summary

Study aim
The aim of this study was to determine the effectiveness of plasmapheresis treatment in comparison with standard treatment in improving the symptoms of high-risk COVID 19 patients.

Design
A clinical trial with a control group, with parallel groups, without blinding, Block randomization, phase 3 on 60 patients.

Settings and conduct
This study was performed on patients with COVID-19 hypoxia despite receiving o2 with bag reservation, spo2 < 94% and after 24 hours of hospitalization provided the criteria for inclusion in the randomized method of block assignment to two groups of 30 intervention And 30 people will be in control

Participants/Inclusion and exclusion criteria
Inclusion criteria: Adults with COVID-19 have high-risk conditions positive laboratory sample Exclusion criteria: Pregnancy History of previous drug allergies AIDS Heart failure Low hemoglobin

Intervention groups
The control group receives only the treatment protocol of the Ministry of Health and the intervention group, after obtaining informed consent and a full explanation of the treatment process to the patient and companions about the treatment process, in addition to receiving the treatment protocol, undergoes plasmapheresis 2 l/d 3 to 5 Meet.

Main outcome variables
Initial outcome (death within 30 days after hospitalization)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160118026097N5**
Registration date: **2020-09-19, 1399/06/29**
Registration timing: **retrospective**

Last update: **2020-09-19, 1399/06/29**
Update count: **0**

Registration date
2020-09-19, 1399/06/29

Registrant information

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Jamshid Vafaeemanesh
Name of organization / entity
Qom University of Medical Sciences
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-03-29, 1399/01/10

Expected recruitment end date
2020-05-30, 1399/03/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effectiveness of plasmapheresis

treatment in comparison with standard treatment in improving the symptoms of high-risk patients

Public title
Effect of plasmapheresis in the treatment of high-risk covid patients in Qom province
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Adults (defined) as older than 18 years and younger than 60 years Laboratory confirmation of Covid19 infection with reverse transcription polymerase chain reaction (RT-PCR) from oropharyngeal or nasopharyngeal swab Covid19-related new organ dysfunction, including hypoxia due to the need for supplemental oxygen to maintain oxygen saturation greater than 94%, hypotension (systolic blood pressure less than 90 mm Hg) or the need for vasopressor, an inotropic drug (Renal impairment (increase in creatinine by more than 50% from baseline, decrease in glomerular filtration rate by more than 25% from onset or urination less than 0.5 ml / kg for 6 hours, decrease in Glasgow scale by 2 or more, ie 13 or less Out of 15 points, thrombocytopenia less than 150,000 platelets per millimeter, gastrointestinal symptoms requiring hospitalization (eg severe nausea, vomiting, diarrhea or abdominal pain)
Exclusion criteria:
Sensitivity or sensitivity to Lopinavir or Ritonavir or recombinant IFN-β1b, including, toxic epidermal necrolysis, Stevens-Johnson syndrome, erythema or angioedema syndrome. Use of drugs that are contraindicated with lopinavir/ritonavir and should not be substituted or discontinued during the study period, such as inhibitors CYP3A Pregnancy-Eligible female participants of childbearing age are tested for pregnancy before enrolling in the study HIV infection is known to cause concern about the resistance to lepinavir / ritonavir if used in combination with other anti-HIV drugs. Hemoglobin under 8 Known heart failure EF under 50% According to the 31st National Guide, all vulnerable groups, such as the mentally disabled, emergency patients, or prisoners, are excluded from the study.
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
does not have

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of qom University of Medical Sciences
Street address
beheshti blv
City
qom
Province
Ghoum
Postal code
3719964797
Approval date
2020-04-19, 1399/01/31
Ethics committee reference number
IR.MUQ.REC.1399.057

Health conditions studied

1

Description of health condition studied
COVID19
ICD-10 code
U07.1
ICD-10 code description
COVID-19, virus identified

Primary outcomes

1

Description
The primary outcome (mortality within 30 days after hospitalization)
Timepoint
After 24 hours in the hospital, every day
Method of measurement
View

Secondary outcomes

1

Description
Days without organ support (for example, supplemental O2, mechanical ventilation, dialysis and vasopressors)
Timepoint
28 days

Method of measurement
View

2

Description
Results of RT-PCR in lower respiratory samples.
Timepoint
Time interval: At the time of entering the study and one week after treatment and repetition every week until the negative sample of the period
Method of measurement
the experiment

3

Description
Body Failure Assessment Scores (SOFA)
Timepoint
Time frame: days 1, 3, 5, 7, 14 and 28)
Method of measurement
check list

4

Description
Long stay at the ICU
Timepoint
A period of one year after discharge
Method of measurement
View file

5

Description
Hospital stay
Timepoint
A period of one year after discharge
Method of measurement
View file

6

Description
Duration of mechanical ventilation
Timepoint
A period of one year after discharge
Method of measurement
View file

7

Description
Chest radiographic findings
Timepoint
Time interval: first and 28 days later (based on pulmonary involvement and radiologist report)
Method of measurement
View file

8

Description
Number of patients with side effects from treatment
Timepoint
Timing: From admission to 28 days, side effects from metabolic treatment such as diabetes, hypothyroidism, hyperlipidemia, rheumatic fever, cataracts, glaucoma, cushingoid complications and gastrointestinal and skin complications
Method of measurement
Examination

9

Description
ICU mortality
Timepoint
A period of one year after discharge
Method of measurement
Phone tracking

10

Description
Hospital mortality
Timepoint
A period of one year after discharge
Method of measurement
Phone tracking

Intervention groups

1

Description
"control group:" receiving the treatment protocol of the Ministry of Health as hydroxychloroquine sulfate tablets 200 mg or two chloroquine phosphate tablets 250 mg and kaletra tablets (lupinavir / ritonavir) 50/200 mg or tablets (atazanavir / ritonavir) 300 / 100 mg.
Category
Treatment - Drugs

2

Description
"The intervention group:" receiving the treatment protocol of the Ministry of Health and plasmapheresis treatment as 2 liters daily for 3 to 5 sessions (Estimated volume of plasma (in liters) = weight 0.07 x (kg) x (1 - hematocrit) and FFP replacement method 4 units, albumin 5 vials, calcium 2 ampoules, the rest of normal serum.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Beheshti Hospital and Forghani-Hedayati Hospital
Full name of responsible person

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Sponsors / Funding sources

1

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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
Ghoum 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
Ghoum University of Medical Sciences
Full name of responsible person
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Position
Associate professor
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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
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All potential data can be shared after people have not been identified
When the data will become available and for how long
Start the access period 6 months after printing the results
To whom data/document is available
Researchers working in academic institutions.
Under which criteria data/document could be used
According to cop rules
From where data/document is obtainable
Refer to the email of the responsible author.
What processes are involved for a request to access data/document
Refer to the email of the responsible author.
Comments
no