Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Nov 2026

The effect of pentaglobin in the treatment of critically ill patients with COVID-19

Protocol summary

Study aim
Evaluation of the efficacy and safety of pentaglobin on patients with COVID-19 infection-induced acute respiratory distress syndrome.

Design
Clinical trial with parallel randomized groups

Settings and conduct
Place of study: Masih Daneshvari Hospital. How to do the study: 30 patients with COVID-19 and other inclusion criteria will be randomly divided in to intervention and control group.

Participants/Inclusion and exclusion criteria
Patients who are diagnosed with COVID-19 by RT-PCR test and are over 18 years old. These patients are included if they have oxygen saturation less than 93%, and not responding to medications in national protocol more than 72 hours, and bilateral pulmonary infiltration.

Intervention groups
In this study patients will receive 5 ml/kg body weight / day Pentaglobin (Biotest company, Germany) for 3 consecutive days with lopinavir-ritonavir (Heterd company, India) at dose of 200/50 mg two tablets BID for 7 days with the standard and supportive care according to national guidelines for COVID-19. Patients in control group only will receive lopinavir-ritonavir (Heterd company, India) at dose of 200/50 mg two tablets BID for 7 days with the standard and supportive care according to national guidelines for COVID-19.

Main outcome variables
Determination of need for supportive treatment with non-invasive oxygen; need for invasive mechanical ventilation; and death.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20151227025726N18**
Registration date: **2020-06-10, 1399/03/21**
Registration timing: **prospective**

Last update: **2020-06-10, 1399/03/21**
Update count: **0**

Registration date
2020-06-10, 1399/03/21

Registrant information

Name
Farzaneh Dastan

Name of organization / entity
Shahid Beheshti University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-06-22, 1399/04/02

Expected recruitment end date
2020-08-23, 1399/06/02

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of pentaglobin in the treatment of critically ill patients with COVID-19

Public title
Pentaglobin effect in critically ill patients with COVID-19

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Laboratory COVID-19 confirmed with RT-PCR who has acute respiratory distress syndrome Severely ill patient Oxygen saturation < 93% Not responding to national protocol after 72 hours Bilateral pulmonary infiltration Signed the consent form
Exclusion criteria:
Chronic kidney disease (stage 4, 5) Chronic liver disease (Child pugh C) Allergy to human immunoglobulins IgA defficiency
Age
From **18 years** old
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **30**
Randomization (investigator's opinion)
Randomized
Randomization description
Block randomization method will be used in this study. Six blocks which each block including 5 patients will be generated by online randomization website. In each block 3 patients will be assigned to pentaglobin group and 2 patients will be assigned to control group, and vice versa.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Vice-Chancellor in Research Affairs - Shahid Beheshti University of Medical Sciences
Street address
3 rd floor, School of Medicine, Evin St, Shahid Chamran Highway
City
Tehran
Province
Tehran
Postal code
1983963113
Approval date
2020-03-10, 1398/12/20
Ethics committee reference number
IR.SBMU.NRITLD.REC.1399.014

Health conditions studied

1

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

Primary outcomes

1

Description
Need for invasive mechanical ventilation
Timepoint
14 and 28 days after therapy initiation
Method of measurement
Medical record

2

Description
Death
Timepoint
14 and 28 days after therapy initiation
Method of measurement
Medical record

3

Description
Supportive treatment with non-invasive oxygen
Timepoint
14 and 28 days after therapy initiation
Method of measurement
Medical record

Secondary outcomes

1

Description
Hospitalization duration
Timepoint
28 days after admission
Method of measurement
Medical records

2

Description
ventilation duration
Timepoint
7 and 14 days after admission

Method of measurement
Medical record

Intervention groups

1

Description
Intervention group: Patients received 5 ml/kg body weight / day Pentaglobin (Biotest company, Germany) for 3 consecutive days. Patients also received standard treatment and supportive care (oxygen therapy and Anticoagulant) according to national guideline for COVID-19.
Category
Treatment - Drugs

2

Description
Control group: Patients will receive lopinavir-ritonavir (Heterd company, India) at dose of 200/50 mg two tablets BID for 7 days with the standard and supportive care (oxygen therapy and Anticoagulant) according to national guidelines for COVID-19.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Masih Daneshvari Hospital
Full name of responsible person
Payam Tabarsi
Street address
Daraabad, Shahid Bahonar St. (Niavaran), Masih Daneshvari Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
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3rd floor, School of Medicine, Evin 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
Payam Tabarsi
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
Infectious diseases
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Person responsible for scientific inquiries

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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
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
Title and more details about the data/document
All potential data can be shared after blinding
When the data will become available and for how long
Six mounts after publishing
To whom data/document is available
Researchers working in academic institutions
Under which criteria data/document could be used
For research purposes and meta-analysis studies
From where data/document is obtainable
Dr. farzaneh Dastan, Dr. Masih Daneshvari Hospital, Daar-Abad, Niavaran
What processes are involved for a request to access data/document
Official letter to the researchers
Comments