

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 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

Country

Iran (Islamic Republic of)

Phone

+98 912 270 5933

Email address

f_dastan@sbmu.ac.ir

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 deficiency

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

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Tehran

Province

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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

Afshin Zarghi

Street address

3rd floor, School of Medicine, Evin St, Shahid

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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

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Farzaneh Dastan

Position

Assistant professor

Latest degree

Specialist

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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 months 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**Person responsible for updating data****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Farzaneh Dastan

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

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