Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Experimental Use of COVID-19 Convalescent Plasma for the Purpose Of Passive Immunization in Current COVID-19 Pandemic

Protocol summary

Study aim
Using COVID-19 convalescent plasma for the purpose of passive immunization in current COVID-19 pandemic

Design
Single arm, open label, clinical trial employing WHO recognized monitored emergency use of unregistered and experimental interventions (MEURI) study design. Sample size is 357

Settings and conduct
The places of the study: National Institute of Blood Disease & Bone Marrow Transplantation, Karachi; Liaquat University of Medical and Health Sciences, Jamshoro, Sindh; University of Health Science and children hospital, Lahore. Blinding in this study: Not Blinded.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: informed consent must have been obtained, confirmed COVID-19 cases confirmed by RT-PCR laboratory tests, moderately severe or severe life-threatening COVID-19 related features: Shortness of breath, respiratory rate ≥ 30/min, arterial blood oxygen saturation ≤ 92%, and/or lung infiltrates > 25% within 24 to 48 hours, Severe Life-threatening disease Exclusion Criteria: Allergy history of plasma, sodium citrate and methylene blue; For patients with history of autoimmune system diseases or selective IgA deficiency, the application of convalescent plasma should be evaluated cautiously by clinicians. Patients having evidence of uncontrolled cytokine release syndrome leading to end-stage multiorgan failure.

Intervention groups
Convalescent plasma: Plasmapheresis, 900 - 1000 mL each time. Standard apheresis plasma collection protocol using Haemonetics MCS+ intermittent blood flow system or Terumo Optia, Cobe-Spectra, Trima or Fresenius continuous flow system to be used. Isovolumic saline replacement should be done. Each donor can donate convalescent plasma again after an interval of every 2 weeks.

Main outcome variables
Shortness of breath, Respiratory rate, Arterial blood oxygen saturation, Lung infiltrates, Respiratory failure, Shock, Multiple organ dysfunction

General information

Reason for update
Responsible person from sponsor updated

Acronym

IRCT registration information
IRCT registration number: **IRCT20200414047072N1**
Registration date: **2020-04-28, 1399/02/09**
Registration timing: **registered_while_recruiting**

Last update: **2020-10-22, 1399/08/01**
Update count: **1**

Registration date
2020-04-28, 1399/02/09

Registrant information

Name
Saba Fatima

Name of organization / entity
Hilton Pharma Pvt. Ltd.

Country
Pakistan

Phone
+92 21 35072224

Email address
sabafatima@hiltonpharma.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-04-14, 1399/01/26

Expected recruitment end date
2021-04-30, 1400/02/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Experimental Use of COVID-19 Convalescent Plasma for the Purpose Of Passive Immunization in Current COVID-19 Pandemic

Public title

Use of Convalescent Plasma in the treatment of COVID-19

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:

Inclusion Criteria for Donors; Volunteer enrollment (Informed consent will be obtained; Annexures-2A & 2B). All the regulations related to ICH-GCP and Blood Transfusion Authority (BTA) Pakistan will be followed. Should fulfill all the criteria of a healthy blood donor (with the exception of history of COVID-19 during last 4-8 weeks. History of COVID-19 during last 4-8 weeks. RT-PCR negative for SARS-CoV-2 RNA (carried out on nasopharyngeal or oropharyngeal specimen). Age cutoff: 18-55 years. Body weight cut off: >50 kg for men and > 45 kg for women. At least a week been passed since last use of glucocorticoids. A minimum of 2-week duration been passed since complete recovery. Inclusion Criteria for Recipients: Volunteer enrollment (Informed consent will be obtained; Annexures-3A & 3B). Confirmed COVID-19 cases confirmed by RT-PCR laboratory tests. Severe or Critical COVID-19 related features (8): (a) Severe COVID-19, defined by the presence of any of the following features: i.Shortness of breath. ii.Respiratory rate ≥ 30/min, iii. Arterial blood oxygen saturation ≤ 93%, iv. Lung infiltrates > 50% within 24 to 48 hours (b) Critical COVID-19, defined by the presence of any of the following features: i.Respiratory failure, ii.Shock iii.Multiple organ dysfunction

Exclusion criteria:

Allergy history for plasma, sodium citrate and methylene blue For patients with history of autoimmune system diseases or selective IgA deficiency, the application of convalescent plasma should be evaluated cautiously by clinicians. Patients having evidence of uncontrolled cytokine release syndrome leading to end-stage multi organ failure.

Age

From **18 years** old to **55 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **357**

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

National Bioethics Committee (NBC) Pakistan

Street address

Pakistan Health Research Council, Shahrah-e-Jamhuriat, Off Constitution Avenue, Sector G-5/2, Islamabad

City

Karachi

Postal code

44050

Approval date

2020-04-04, 1399/01/16

Ethics committee reference number

4-87/NBC-COVID19-/20/03

Health conditions studied

1

Description of health condition studied

COVID-19

ICD-10 code

U07.1

ICD-10 code description

COVID-19, virus identified

Primary outcomes

1

Description

Fever

Timepoint

registration day and week 4

Method of measurement

thermometer will be used for physical examination to check fever.

2

Description

Resolution of infection

Timepoint

28 days

Method of measurement

Two non-reactive Nucleic Acid Tests (NAT) for SARS-CoV-2 performed at an interval of at least 24 hours on nasopharyngeal swabs

3

Description

Lung infiltrates

Timepoint

registration day and week 4

Method of measurement

X-ray will be used

4

Description

Arterial blood oxygen saturation

Timepoint

registration day and week 4

Method of measurement

Lab test (blood from artery will used)

5

Description

Respiratory rate

Timepoint

registration day and week 4

Method of measurement

physical examination was conducted to measure the breath rate by counting chest or abdomen rises number over a minute.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Convalescent Plasma, Frozen Solution for infusion (FFP) for the prevention and treatment of Covid-19. Human plasma protein. The dosage depends upon the clinical situation and underlying disorder, use within 24 hours, administration based on ABO-blood group compatibility. Avoid shaking. It should be frozen within 8 hours after collection, stored at -18C or colder and have an expiration date one year from the date of collection. Not to exceed IV infusion rate of 1 mL/kg/min, emergency IND (eIND) approved by FDA. provided by Blood bank of the hospital mentioned in the IRB.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

National Institute of Blood Disease & Bone Marrow Transplantation

Full name of responsible person

Professor Dr. Tahir S Shamsi

Street address

ST 2/A Block 17 Gulshan-e-Iqbal KDA Scheme 24 Karachi, Pakistan.

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Karachi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hilton Pharma Pvt. Ltd.

Full name of responsible person

Shahbaz Malik

Street address

Progressive Plaza, 8-9th floor Beaumont Road, Near P.I.D.C House, Karachi, Pakistan

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Fax

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shahbaz@hiltonpharma.com

Grant name

Research Grant

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Hilton Pharma Pvt. Ltd.

Proportion provided by this source

40

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Industry

2

Sponsor

Name of organization / entity
National Institute Of Blood Disease and Bone Marrow Transplantation

Full name of responsible person
Professor Dr. Tahir S Shamsi

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Grant name
Research Grant

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
National Institute Of Blood Disease and Bone Marrow Transplantation

Proportion provided by this source
60

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Other

Person responsible for general inquiries

Contact

Name of organization / entity
National Institute Of Blood Disease and Bone Marrow Transplantation

Full name of responsible person
Dr. Arshi Naz

Position
Assistant Professor and Scientific Manager

Latest degree
Ph.D.

Other areas of specialty/work
Dip in lab Sciences

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Other areas of specialty/work
Dip in lab Sciences

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Person responsible for updating data

Contact

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Position
Senior Officer, Medical Affairs

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Bachelor

Other areas of specialty/work
Medical Pharmacy

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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
Not applicable

Informed Consent Form
No - There is not 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
Not applicable

Data Dictionary
Not applicable