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Effectiveness and safety of plasma convalescent therapy in patients with COVID-19

Submission date
28/09/2020

Recruitment status
No longer recruiting

Registration date
10/11/2020

Overall study status
Completed

Last Edited
10/11/2020

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
COVID-19 is a condition caused by the coronavirus (called SARS-CoV-2) that was first identified in late 2019. This virus can infect the respiratory (breathing) system. Some people do not have symptoms but can carry the virus and pass it on to others. People who have developed the condition may develop a fever and/or a continuous cough among other symptoms. This can develop into pneumonia. Pneumonia is a chest infection where the small air pockets of the lungs, called alveoli, fill with liquid and make it more difficult to breathe.
In 2020, the virus has spread to many countries around the world and neither a vaccine against the virus or specific treatment for COVID-19 has yet been developed. As of April 2020, it is advised that people minimize travel and social contact, and regularly wash their hands to reduce the spread of the virus.
Groups who are at a higher risk from infection with the virus, and therefore of developing COVID-19, include people aged over 70 years, people who have long-term health conditions (such as asthma or diabetes), people who have a weakened immune system and people who are pregnant. People in these groups, and people who might come into contact with them, can reduce this risk by following the up-to-date advice to reduce the spread of the virus.
Convalescent plasma (plasma from a recovered COVID-19 patient) is a promising treatment for COVID-19. The aim of this study is to evaluate the safety and effectiveness of convalescent plasma for COVID-19 in Indonesia.

Who can participate?
Moderately, severely and critically ill COVID-19 patients

What does the study involve?
Patients who receive convalescent plasma with standard treatment are compared with patients who receive standard treatment only. The mortality (death) rate is measured using a phone call to the family after 2 months follow up.

What are the possible benefits and risks of participating?
Patients given plasma convalescent may receive immunity from COVID-19 and rapid recovery from infection. Risks include allergy, anaphylactic shock, TRALI (transfusion-related acute lung injury), and TRACO (transfusion-associated circulatory overload).

Where is the study run from?
Dr Kariadi Hospital (Indonesia)

When is the study starting and how long is it expected to run for?
April 2020 to December 2020

Who is funding the study?
BRIN (Ministry of Research and Technology)/LPDP (Educational Fund Management Institution) (Indonesia)

Who is the main contact?
Dr Damai Santosa
santosaivha@fk.undip.ac.id

Contact information

Type(s)
Scientific

Contact name
Dr Damai Santosa

ORCID ID
https://orcid.org/0000-0002-6093-5049

Contact details
Jl. DR. Sutomo No.16, Randusari
Kec. Semarang Sel.
Kota Semarang
Jawa Tengah
Semarang
Indonesia
50244
+62 (0)81325062592
santosaivha@fk.undip.ac.id

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
003

Study information

Scientific Title
Efficacy and safety of convalescent plasma transfusion administered as adjunctive treatment to standard treatment in moderate, severe, and/or critically ill patients with COVID-19

Study objectives
There is an effect of convalescent plasma on moderate, severe, and/or critically ill patients with COVID-19.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 09/05/2020, Ministry of Health-National Institute of Health Research and Development (Jl Percetakan Negara No. 29 Jakarta 10560, Postcode: 1226; +62 (0)214261088; scsban@litbang.depkes.go.id), ref: LB.02.01/KE 351/2020

Study design
Non-randomized trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
COVID-19 (SARS-CoV-2 infection)

Interventions
Patients are given convalescent plasma (200 ml with IgG SARS-CoV-2 level of 1/80) intravenously as an adjunctive treatment to standard treatment.

For the control group, the researchers use a historical control group that matches with the treatment group.

Total treatment duration: 5 days
Total follow up: 2 months

Intervention Type

Biological/Vaccine

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Convalescent plasma

Primary outcome measure
Mortality rate measured using a phone call to the family after 2 months follow up

Secondary outcome measures
1. Duration on ventilator measured as the time from intubation to the time of final extubation (days)
2. Length of stay measured by the duration of a single episode of hospitalization (days)
3. Organ failure measured using SOFA score at the day before transfusion, day 1, day 2, and day 7 after convalescent plasma administration 0-24)
4. Levels of F-VIII measured using 2 stage assays at the day before transfusion, day 1, day 2, and day 7 after the convalescent plasma administration
5. Levels of IgG antibody SARS-CoV-2 measured by chemiluminescence microparticle immunoassay (CMIA) on the day before transfusion, day 1, day 2, and day 7 after the convalescent plasma administration
6. Levels of coagulation parameter (D-Dimer) measured by agglutination at the day before transfusion, day 1, day 2, and day 7 after the convalescent plasma administration
7. Levels of IL- 6 measured by enzyme immunoassays at the day before transfusion, day 1, day 2, and day 7 after the convalescent plasma administration

Overall study start date
26/04/2020

Completion date
13/12/2020

Eligibility

Key inclusion criteria
1. Confirmed COVID-19
2. Clinically moderate, severe, and/or critically ill

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
5

Key exclusion criteria
1. History of allergy to plasma
2. Patient with an estimated poor prognosis with sofa score >11, risk of mortality 53%

Date of first enrolment
19/05/2020

Date of final enrolment
12/12/2020

Locations

Countries of recruitment
Indonesia

Study participating centre
Dr Kariadi Hospital
Jl. Dr. Sutomo no 16
Semarang
Indonesia
50244

Sponsor information

Organisation
Ministry of Research and Technology/National Research and Innovation Agency (Kementerian Riset dan Teknologi Republik Indonesia)

Sponsor details
Gedung BPPT II lantai 24, Jl. M.H. Thamrin No. 8
Jakarta
Indonesia
10310
+62 (0)1500661
hkli.risbang@ristekbrin.go.id

Sponsor type
Government

Website
https://www.ristekbrin.go.id/

Funder(s)

Funder type
Government

Funder Name
KEMENRISTEK/BRIN Indonesia

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
20/12/2020

Individual participant data (IPD) sharing plan
Data will be available upon request from Ika Kartiyani (ikakartiyani@gmail.com).

IPD sharing plan summary
Available on request