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

Submission date 28/09/2020	Recruitment status No longer recruiting	 Prospectively registered Protocol
Registration date 10/11/2020	Overall study status Completed	 Statistical analysis plan Results
Last Edited 10/11/2020	Condition category Infections and Infestations	Individual participant dataRecord 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

 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
 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

Key exclusion criteria

History of allergy to plasma
 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