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Using blood plasma to develop passive immunity to coronavirus in Ecuador

Submission date
06/05/2020

Recruitment status
No longer recruiting

Registration date
11/05/2020

Overall study status
Completed

Last Edited
08/05/2020

Condition category
Respiratory

[ ] 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.

Passive immunity is a treatment used in medicine when there are no specific treatments or vaccines available for an infectious disease, such as COVID-19, whereby antibodies (proteins that are produced by the body to fight infection) are transferred to a patient, rather than the patient generating these antibodies themselves. Previous studies have shown that the use of plasma from patients who have recovered from an infection, convalescent plasma (CP), is beneficial to patients who have recently been infected.

In a recent publication, 5 patients with COVID-19 were shown to have an improvement in their clinical status following the administration of CP from patients previously infected and now recovered from COVID-19. Better results have been observed for treatment with CP when it is administered early in infection. These data suggest that the administration of CP for COVID-19 patients has positive effects. However, further clinical trials are needed to show whether this treatment is effective and safe.

The aim of this study is to evaluate the safety and efficacy of CP for COVID-19 patients when used as an additional/complementary treatment to standard care in patients with clinical deterioration.

Who can participate?
Adult patients with a diagnosis of COVID-19 and worsening lung function

What does the study involve?
Participants will receive either convalescent plasma from a patient who has recovered from COVID-19, or regular plasma, given into the vein. This treatment would be given in addition to

the standard treatment of their SARSCoV2 infection. Participant's health will then be monitored for 21 days or until they are able to leave the hospital.

What are the possible benefits and risks of participating?
Administration of convalescent plasma may help to increase a participant's immune defense against infection immediately until their body makes its own defenses. These defenses boost the immune system and may help fight the virus that causes COVID-19.

While plasma transfusion is a simple and safe process, there is a small chance that unwanted side-effects can happen. The investigators will monitor participants for these side effects. The most frequently seen side effects are mild, very rarely they can be serious and compromise the life of the participant, these include reaction with fever, with chills (1-2% of patients), allergic reaction, with hives (swelling), erythema (red spot), itching (itching) (1-2% of patients), hypertension (high blood pressure) and heart failure. Side effects that are infrequent, but can pose a risk to the patient include circulatory overload with respiratory failure, transfusion-associated acute lung injury, sensitization problems with destruction of platelets or red blood cells (hemolysis), hemolytic transfusion reaction with serious organic repercussions, bacterial contamination (infection), serious allergic reaction, and incompatibility of group A B O, Rh, or other blood subgroups.

Where is the study run from?
Universidad UTE (Ecuador) and Cruz Roja Ecuatoriana (Ecuador)

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

Who is funding the study?
SalvarVidasEC (Ecuador)

Who is the main contact?
Dr Manuel Baldeon
manuel.baldeon@ute.edu.ec

Contact information

Type(s)
Scientific

Contact name
Dr Manuel Baldeon

ORCID ID
https://orcid.org/0000-0002-1243-7467

Contact details
Av. Mariscal Sucre S/N y Av. Mariana de Jesús
Bloque "I"
Planta Alta
Quito
Ecuador
170129

+593 983356787
manuel.baldeon@ute.edu.ec

Additional identifiers

Study information

Scientific Title
Investigating the use of convalescent plasma from patients who have recovered from COVID-19 in the management of Ecuadorian patients infected with SARS-CoV-2 with clinical deterioration: IMPACT

Acronym
IMPACT

Study objectives
Administration of convalescent plasma from individuals recovered of COVID-19 to critically ill patients infected with SARS-CoV-2 will decrease patient mortality compared to patients that will receive non-immune plasma.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/04/2020, Institutional Review Board of Universidad San Francisco de Quito (Campus Cumbayá, Diego de Robles s/n, Quito 170901, Ecuador; comitebioetica@usfq.edu.ec; +593 2-297-1700), ref: CEISH 2020-025M

Primary study design
Interventional

Study design
This is a triple-blinded, two-arm, randomised controlled clinical trial

Study type(s)
Treatment

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

Interventions
Patients who meet the inclusion and exclusion criteria will be allocated into the study by simple randomization generated by random numbers with the SPSS software to one of the two treatment groups:
1. Group 1 (G1) will receive standard therapy for COVID-19 (SARS-CoV-2 infection) and immune plasma from convalescent patients (PC)
2. Group 2 (G2) will receive standard therapy against COVID-19 (SARS-CoV-2 infection) and non-immune plasma

Patients will receive 5mL of plasma/Kg of body weight intravenous (IV) for one occasion.

Patients will be followed up daily for 21 days or until the day of hospital discharge before the 21 days. If patients require a longer hospital stay, data from the patients will be collected at the time of discharge too. The clinical status of the patient will be assessed before the start of therapy (baseline) and on days 1, 3, 7, 14, and 21. SOFA, thoracic X-ray and/or tomography if possible will also be documented at discharge.

Intervention Type
Biological/Vaccine

Phase
Phase II/III

Drug/device/biological/vaccine name(s)
Convalescent plasma obtained from previously infected and recovered COVID-19 patients

Primary outcome(s)
Case fatality rate assessed through data collected from the follow-up instrument and medical record at 21 and 28 days

Key secondary outcome(s)
1. Demographic information, including age and sex will be collected using the specific instrument created to screen potential patients at baseline
2. Time of initiation of treatment in relation to the evolution of the disease assessed using the follow-up instrument which is completed daily from baseline to 21 days
3. Adverse reactions and interaction with other treatments, assessed through the medical record and follow-up instrument at the time of these events
4. Clinical recovery time assessed by the follow-up instrument which is completed daily from baseline to 21 days
5. Sequelae at discharge (liver, kidney functions, pulmonary, cardiac and neurological) assessed by the follow-up instrument at discharge
6. Hospitalization time, defined as time from admission until discharge from the hospital or death of the patient, assessed through clinician notes at the time of these events and the follow-up instrument

Completion date
31/12/2020

Eligibility

Key inclusion criteria
1. Aged ≥18 years
2. Clinical, molecular (using IgM/IgG or RT-PCR), or lung imaging diagnosis of COVID-19
3. Deterioration of previously normal lung function defined as SaO2 of <90% in 0.5 FiO2, and/or a higher requirement of O2 than in the previous 24h
4. A score of 5 to 7 on the early warning scale for COVID-19 patients or a SOFA score between 2 and 10
5. Informed consent provided by patients or their representatives

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Diagnosis and/or treatment for cancer
2. HIV infection
3. Currently receiving immunosuppressants for a condition other than SARS-CoV2 infection
4. Superimposed systemic infections
5. Liver or kidney failure
6. COPD, previous pulmonary fibrosis, and/or restrictive lung disease
7. Have received previous transfusions

Date of first enrolment
10/05/2020

Date of final enrolment
31/10/2020

Locations

Countries of recruitment
Ecuador

Study participating centre
Cruz Roja Ecuatoriana
Sede Central
Antonio Elizalde E4-31
Av. Gran Colombia
Quito
Ecuador
170403

Sponsor information

Organisation
Universidad Tecnológica Equinoccial

ROR
https://ror.org/00dmdt028

Funder(s)

Funder type
Charity

Funder Name
SalvarVidasEC

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analyzed during the current study are/will be available upon request from Manuel E. Baldeon (manuel.baldeon@ute.edu.ec). All results will be available once the study will be concluded and data analyzed; data will be available for 6 months after publication. Data will be shared with scientists only with scientific purposes upon a written formal request. All participants have signed an informed consent. All data will be coded from the beginning of the study. Current study follows international and local ethics regulations.

IPD sharing plan summary
Available on request