16/06/2020

# TREATMENT OF CRITICALLY ILL PATIENTS WITH COVID-19 WITH CONVALESCENT PLASMA

NCT04468009

INFORMED CONSENT FOR PLASMA DONOR

# Informed consent of blood donors

## Title of research project: **"Treatment of critically ill patients with COVID-19 with convalescent plasma**"

The disease caused by severe acute respiratory syndrome (SARS) coronavirus 2 (COVID-19) is an infectious disease that has become a major concern worldwide, having been declared a pandemic by the World Health Organization. The clinical characteristics of this disease are highly variable, cases are described as mild in 81%, severe cases in 14%, critical disease in 14%, with a mortality rate of 2.3%.

Since at the moment there is no specific treatment approved for this disease, there is a great interest in carrying out research regarding the use of convalescent plasma for the treatment of COVID-19, with Dr. Carlos Alberto González as the principal investigator.

When a person contracts a virus such as SARS Cov 2, their immune system creates antibodies to fight the virus. These antibodies can be found in plasma, the liquid part of the blood. The plasma with these antibodies that fight infections is known as "convalescent plasma". Through a blood donation process, this plasma rich with antibodies can be collected from persons who have recovered and then transfused to a sick patient as it could help accelerate their recovery process.

Huma convalescent plasma has been successfully used for the prevention and treatment of other infections and, therefore, could provide a therapeutic option of COVID-19, associated to the advantage of its availability through plasma donation of people who have recovered of the disease. Since there is no certainty that this treatment works in patients with diagnosis of COVID- 19, the Hospital Muñiz is carrying out a Clinical Trial to prove the efficacy of the treatment with convalescent plasma COVID-19.

In order to be able to develop this Clinical Trial we need your collaboration as a blood donor (following the guidelines from National Blood Law N° 22.990, specially the statements in chapter XV, its regulatory decree 375/89 and Resolution N° 797/2013). Nonetheless, to be included as a collaborator you must meet certain requirements. Firstly, to have suffered COVID-19 disease and to have recovered from it. Secondly, to answer a questionnaire about acute or chronic previous diseases and also about certain habits and customs. These requirements are necessary to evaluate your condition as a potential donor. You should know that all the information that is obtained will be properly anonymized with the aim of safeguarding the most complete confidentiality.

All the information that you provide, as well as the results of the test, will be treated confidentially. The data obtained may not be used for other purposes than those that motivated its collection and the researchers will preserve the identity of the data holders through dissociation mechanisms (the information may not be associated, with the exception of scientific reasons, with a specific or determinable person). In addition, the person who will receive the transfusion will not know who gave the blood. Your identity will be protected.

The procedure that will be performed consists of drawing blood from a vein. Later, your blood will be separated in different components: red blood cells, platelets, white blood cells. Hematomas may appear at puncture site. Other manifestations that may occur are: dizziness, nausea or vomiting, which are transient, and exceptionally fainting, seizures, arrhythmias and infection. You should know that it is a routine procedure In the Blood Bank and that the professionals in charge will take all measures to minimize the occurrence of unwanted effects and to treat possible complications through therapeutic and pharmacological methods, if your authorization is given.

It may also occur that after the procedure your platelets, red blood cells and plasma may be temporarily reduced to a level that does not imply a risk to your health, since they are regenerated by your body immediately. However, remember that your participation is free and voluntary. There will be no financial costs for you in anything related to this donation and neither will you receive any payment for your collaboration as a convalescent plasma donor. Furthermore, you have the right to discontinue your donation in any of its instances, revoking

your consent whenever you consider it necessary. The plasma units obtained from the blood you donate will be exclusively transfused to patients included in the research protocol, although they may also be administered to critically ill patients according to the "compassionate use" figure provided by international regulations in research ethics, therefore combining research with healthcare.

At the end of this study, you may be informed of the conclusions obtained, since the results will be communicated openly and free of charge to all health professional and, in general, to the community.

Place and date
I……
DNI…….…..……. express my consent to participate as a donor of the Clinical Trial for the treatment of the disease by the virus of the COVID-19. I have been able to carefully read the text and I have understood the information regarding its nature, scope and probable undesired effects. I have also been able to make all the questions that I considered necessary and they were answered in a clear and understandable way.
Therefore, I authorize the blood extraction, voluntarily, altruistically and free of charge, for therapeutic and research purposes. I also authorize, if necessary, the corresponding procedures to treat the possible secondary effects of the extraction.

Name and Surname: DNI: Signature
Name and Surname of the responsible professional:
Matricula:
Firma:

| | |
|---|---|
| **Principal Investigator:** | Dr. Carlos González,<br>Hemotherapy and Immunohematology Service,<br>Uspallata 2272 –<br>Telephone 4305 7893 int.224<br>Email: carlosgonzalez@buenosaires.gob.ar |
| **Research Ethics Committee** Hospital F. J. Muñiz – | Uspallata 2272 – First floor<br>Telephone 4304-2180 intern 268<br>Monday to Friday from 8:30 to 14<br>Email: muniz_cei@buenosaires.gob.ar |
| **Teaching and Research Committee** Hospital F. J. Muñiz | Uspallata 2272 –<br>Telephone 4304-0357 interno 255 |

**Don't sign this document unless you have had the chance to ask all your neccessary questions to the physician**

16/06/2020

# TREATMENT OF CRITICALLY ILL PATIENTS WITH COVID-19 WITH CONVALESCENT PLASMA

NCT04468009

INFORMED CONSENT FOR PATIENTS RECEIVING STANDARD OF CARE

# RESEARCH PROJECT INFORMATION SHEET

Title of research project: **"Treatment of critically ill patients with COVID-19 with convalescent plasma"**

Hospital de Infecciosas Francisco Javier Muñiz
Principal Investigator: Dr. Carlos Alberto González
Hemotherapy and Immunohematology Service
Uspallata 2272 – Ciudad Autónoma de Buenos Aires
Telephone 4305 7893 int.224
Email: carlosgonzalez@buenosaires.gob.ar
muniz_cei@buenosaires.gob.ar

You have been invited to participate in a research project on COVID-19 treatment.

Take the time you consider necessary to carefully read this information sheet that will be analysed by you and the physician. Before deciding whether you accept or not to participate, it is essential that you are aware of the reasons why this research is being carried out and your participation in it. You have the opportunity to ask all the necessary questions to the physician and he/she will provide you with the necessary information.

Once you understand what the research project is about, the risks and benefits, you will be able to make the decision to participate or not to participate in this research project. In the event that you decide to participate, you will receive this information sheet and a copy of the consent form, which you must keep.

You / your son / a member of your family has been diagnosed with COVID-19 disease. The disease by SARS CoV-2 virus is a disease transmitted through close contact with saliva and nasal discharge from infected people. Some of the symptoms of the disease include fever, cough, headache, and shortness of breath. The disease may be severe and lead to the death of elderly patients or people with other health problems.

With the exception of some experimental treatments, there is currently no treatment or vaccine available to treat or prevent COVID-19. If a treatment for COVID-19 would be found, it would save many lives. The people that have recovered from COVID-19, did so because their body could fight the disease and now their blood has substances capable to fight the SARS CoV 2 virus. This ability, in all likelihood, remains for several months. We believe that the patients that currently have the disease could improve faster if they received plasma (the liquid part of the blood) which has the ability to fight the virus. However, we don't know this for sure. It is possible that a patient with COVID-19 does not recover even after receiving blood from someone who has recovered from COVID-19. Since we currently have no other therapeutic option, we would like to try.

We are asking you if you would like to participate in this clinical trial, in which some patients will be administered blood or plasma obtained from a person who has recovered from COVID-19 as an empirical treatment.

We don't know if this treatment will help him/her or not, and we don't know if it will have a harmful effect. This is the only treatment that we currently have, but you should know that it hasn't been tested in humans yet. Since we currently don't have another option of treatment, we would like to try it and learn from the tests.

**Purpose of the project**

The aim of this research project is to test a new therapy and to learn more about its effects on humans and we will record as much information about you and your response to the treatment as possible.

You may choose to receive this treatment or not. Your choice will not affect the attention you are receiving in the centre. We will always make our best effort to take care of you. If you enrol in this treatment, you will also help us to know if the treatment works and how it works to help other patients, and you may withdraw at any time.

If you decide to withdraw your participation in the research, you will receive the same treatment as other patients with the same disease.

**Eligibility**:

Men and women from 18 years of age may participate in this research project.

**Procedures**

You / your son / member of your family will receive standard of care and it will help us to compare it with patients that will receive convalescent plasma.

There are no scheduled visits in this project and the information will be obtained from routine medical examinations.

The physician conducting the project and the his/her staff will record information regarding your health, including diseases you have or medications you were receiving, even those over-the-counter.

In order to protect your privacy a code to identify your data will be used. This code will make it very hard for your information to be linked to you. While you are participating in this project, you may be offered other related investigations. Your refusal will not affect participation in this project.

**Risks and/or inconveniences**

There are no added risks to your participation in this research project, additional blood samples may be taken if necessary.

**Benefits**:

We cannot promise you that participating in this research project will help you since we are not sure how good standard of care is to treat COVID-10 disease. Nevertheless, we believe that this treatment may be effective in improving the likelihood that you recover from infection.

**Free of charge**

During the research project, you will not have to pay for any laboratory tests, medical visits, treatments or diagnoses related to the project.

**Voluntary participation:**

It is vital that you know that your participation is completely voluntary. You have the right not to participate, or to withdraw from the project at any time, and this decision will not affect your medical attention, you will not be discriminated, penalized or harmed by it in our Hospital.

The signing of the informed consent does not imply the loss of the rights that legally correspond to you according to the laws in force in Argentina.

Your participation in the study may be suspended for any of the following reasons:

- You decide not to continue participating, without having to give reasons.
- The Institution decides to suspend the research project in this centre.

**Confidentiality**

The information in this research project will be confidential in accordance with current law. You will be identified by a code and only the research team, CEI members and health authorities may have access to the personal information in your medical file, which are committed to safeguarding your privacy and the confidentiality of your personal data. Your personal information regarding personal history will be used in encrypted form.

All relevant information to you, including a synthesis of the final results of the research, will be provided by the Principal Investigator.

In no publication about the research project will you be personally identified. Only researchers and designated collaborators and representatives of the ethics committee will have access to your medical data, which will be stored on encrypted magnetic media.

**If you have any doubts about your rights as a research subject or about your participation in the study, you can contact:**

| | |
|---|---|
| **Principal Investigator:** | Dr. Carlos González,<br>Hemotherapy and Immunohematology Service,<br>Uspallata 2272 –<br>Telephone 4305 7893 int.224<br>Email: carlosgonzalez@buenosaires.gob.ar |
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# INFORMED CONSENT FORM OF THE RESEARCH PROJECT

**Title of the Research Project: "Treatment of critically ill patients with COVID-19 with convalescent plasma"**

Hospital de Infecciosas Francisco Javier Muñiz
Principal Investigator: Dr. Carlos Alberto González
Hemotherapy and Immunohematology Service
Uspallata 2272 – Ciudad Autónoma de Buenos Aires
Telephone 4305 7893 int.224
Email: carlosgonzalez@buenosaires.gob.ar
muniz_cei@buenosaires.gob.ar

**Patient Nº:**
**Name and surname:**
**Initials:**
**Date of birth:**
**DNI:**
**Residence:**
**Telephone:**

I, ……..(Name and surname of the participant, handwritten) declare that I have read and understood the information sheet and to have been given by Dr/a.……..(Name and surname of the physician that takes the informed consent) enough information about this research project. I have been able to ask freely all necessary questions and received clarification regarding all my doubts. By giving my consent, I understand that my participation is voluntary and that I may refuse or withdraw from participating at any time without sanction nor loss of benefits to which I am entitled.
I understand that I will not lose any of my legal rights granted by Argentinian law as a research subject by signing this informed consent I or my representative authorized by law (if applicable) will receive an information sheet and a copy fully signed and dated of this informed consent form.
I express my free consent to participate in this research.

**Signature participant**: **Name and Surname**:
D.N.I.
Place and date:

**Signature witness ****: **Name and Surname**:
D.N.I.
Place and date:

**Signature Investigator:** **Name and Surname**:
D.N.I.
Place and date:

As the Principal Investigator and Coordinator of the research project, I promise to carry out the approved protocol, Law 3301, its Regulatory Decree, and all other regulations related to the Research protocol, adhering to the values and ethical principles universally proclaimed and cited in this Law and to respect the rights of the subjects participating in this research project while it is carried out.
** The witness must be present at the moment the investigator or the person who obtains the informed consent explains its content to the participant.

16/06/2020

# TREATMENT OF CRITICALLY ILL PATIENTS WITH COVID-19 WITH CONVALESCENT PLASMA

NCT04468009

INFORMED CONSENT FOR PATIENTS RECEIVING PLASMA

# RESEARCH PROJECT INFORMATION SHEET

Title of research project: **"Treatment of critically ill patients with COVID-19 with convalescent plasma"**

Hospital de Infecciosas Francisco Javier Muñiz
Principal Investigator: Dr. Carlos Alberto González
Hemotherapy and Immunohematology Service
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You have been invited to participate in a research project on COVID-19 treatment.

Take the time you consider necessary to carefully read this information sheet that will be analysed by you and the physician. Before deciding whether you accept or not to participate, it is essential that you are aware of the reasons why this research is being carried out and your participation in it. You have the opportunity to ask all the necessary questions to the physician and he/she will provide you with the necessary information.

Once you understand what the research project is about, the risks and benefits, you will be able to make the decision to participate or not to participate in this research project. In the event that you decide to participate, you will receive this information sheet and a copy of the consent form, which you must keep.

You / your son / a member of your family has been diagnosed with COVID-19 disease. The disease by SARS CoV-2 virus is a disease transmitted through close contact with saliva and nasal discharge from infected people. Some of the symptoms of the disease include fever, cough, headache, and shortness of breath. The disease may be severe and lead to the death of elderly patients or people with other health problems.

With the exception of some experimental treatments, there is currently no treatment or vaccine available to treat or prevent COVID-19. If a treatment for COVID-19 would be found, it would save many lives. The people that have recovered from COVID-19, did so because their body could fight the disease and now their blood has substances capable to fight the SARS CoV 2 virus. This ability, in all likelihood, remains for several months. We believe that the patients that currently have the disease could improve faster if they received plasma (the liquid part of the blood) which has the ability to fight the virus. However, we don't know this for sure. It is possible that a patient with COVID-19 does not recover even after receiving blood from someone who has recovered from COVID-19. Since we currently have no other therapeutic option, we would like to try.

We are asking you if you would like to be administered blood or plasma obtained from a person who has recovered from COVID-19 as an empirical treatment for you / your son / member of your family.

We don't know if this treatment will help you or not, and we don't know if it will have a harmful effect. There is no known effective treatment to date, it could be helpful, but you should know that it has not been tested in humans yet.

**Purpose of the project**

The aim of this research project is to test a new therapy and to learn more about its effects on humans and we will record as much information about you and your response to the treatment as possible.

You may choose to receive this treatment or not. Your choice will not affect the attention you are receiving in the centre. We will always make our best effort to take care of you. If you enrol in this treatment, you will also help us to know if the treatment works and how it works to help other patients, and you may withdraw at any time.

If you decide to withdraw your participation in the research, you will receive the same treatment as other patients with the same disease.

**Elegibility**:

Men and women from 18 years of age may participate in this research project.

**Procedures**

You / your son / member of your family will receive blood or the liquid part of the blood from a person that has recovered from COVID-19. It will be administered into a vein, using a sterile single-use needle, and it will be administered in approximately one hour. Approximately 200 ml of plasma will be administered 2 or 3 times. According to the tests that will be carried out in your blood / your son's blood / member of your family after this treatment, it may be repeated in the following days with blood or plasma from different donors.

There are no scheduled visits in this project and the information will be obtained from routine medical examinations.

The physician conducting the project and the his/her staff will record information regarding your health, including diseases you have or medications you were receiving, even those over-the-counter.

In order to protect your privacy a code to identify your data will be used. This code will make it very hard for your information to be linked to you. While you are participating in this project, you may be offered other related investigations. Your refusal will not affect participation in this project.

**Risks and/or inconveniences**

There is little experience with transfusion of plasma from people who have recovered from SARS CoV 2, from experiences in other countries and according to what we have seen in other diseases, the risk would be very low and not at all expected.

The transfusion also implies the risk of adverse reactions and transfusion-transmitted infections, such as HIV and hepatitis B and C, although the risk is low since only properly studied and compatible blood and blood products are used for transfusion.

**Benefits**:

We cannot promise you that this treatment will help you because we are not sure how good convalescent blood or plasma is in treating COVID 19 disease. Nevertheless, we believe that this treatment may be effective in improving the likelihood that you recover from infection.

**Free of charge**

During the research project, you will not have to pay for any laboratory tests, medical visits, treatments or diagnoses related to the project.

**Voluntary participation:**

It is vital that you know that your participation is completely voluntary. You have the right not to participate, or to withdraw from the project at any time, and this decision will not affect your medical attention, you will not be discriminated, penalized or harmed by it in our Hospital.

The signing of the informed consent does not imply the loss of the rights that legally correspond to you according to the laws in force in Argentina.

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You will be identified by a code and only the research team, CEI members and health authorities may have access to the personal information in your medical file, which are committed to safeguarding your privacy and the confidentiality of your personal data. Your personal information regarding personal history will be used in encrypted form.

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Principal Investigator: Dr. Carlos Alberto González
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Telephone 4305 7893 int.224
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**Patient Nº:**
**Name and surname:**
**Initials:**
**Date of birth:**
**DNI:**
**Residence:**
**Telephone:**

I, ……..(Name and surname of the participant, handwritten) declare that I have read and understood the information sheet and to have been given by Dr/a……..(Name and surname of the physician that takes the informed consent) enough information about this research project. I have been able to ask freely all necessary questions and received clarification regarding all my doubts. By giving my consent, I understand that my participation is voluntary and that I may refuse or withdraw from participating at any time without sanction nor loss of benefits to which I am entitled.
I understand that I will not lose any of my legal rights granted by Argentinian law as a research subject by signing this informed consent I or my representative authorized by law (if applicable) will receive an information sheet and a copy fully signed and dated of this informed consent form.
I express my free consent to participate in this research.

**Signature participant**: **Name and Surname**:
D.N.I.
Place and date:

**Signature witness ****: **Name and Surname**:
D.N.I.
Place and date:

**Signature Investigator:** **Name and Surname**:
D.N.I.
Place and date:

As the Principal Investigator and Coordinator of the research project, I promise to carry out the approved protocol, Law 3301, its Regulatory Decree, and all other regulations related to the Research protocol, adhering to the values and ethical principles universally proclaimed and cited in this Law and to respect the rights of the subjects participating in this research project while it is carried out.
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