COVID-19 anti-CD14 CaTT Treatment Trial

MASTER CONSENT

Study Title: **Phase 2, Randomized, Double-Blind, Placebo-Controlled Study of the Effect of Anti-CD14 Treatment in Patients with SARS-CoV-2 (COVID-19)**

Version Date: **January 21, 2021**

INFORMATION ABOUT A RESEARCH STUDY

What is this study hoping to learn?

We are studying a new way to treat patients who are sick with COVID-19, which is caused by the SARS-CoV-2 virus. We think that worsening of the disease is due to the body's reaction to the virus. This reaction can cause worsening lung symptoms. These symptoms can include shortness of breath, low blood oxygen, and lung infection.

This is a research study of an experimental drug called IC14 that is not yet approved by the Food and Drug Administration (FDA). IC14 may reduce the body's reaction to the virus. If the reaction is less, the lungs and other organs should do much better. IC14 has not been studied yet in patients with COVID-19.

By doing this study, we hope to learn:

- if the IC14 study drug will be helpful to treat COVID-19
- what the side effects of IC14 are when taken for COVID-19

What will you be asked to do if you agree to be in the study?

- You will be in this study for about 60 days.
- You will receive IC14 antibody or saltwater by intravenous (IV) (a needle in your vein) infusion daily for 4 days. You will not feel it being given.
- Everyone in the study will receive an antiviral drug called remdesivir by intravenous (IV) infusion for 5 days. This drug is FDA approved for treating COVID. You could get remdesivir even if you are not in this study.
- Draw blood and record your blood test results.
- Collect Nose Samples
- Have two chest x-rays
- Fill out a Questionnaire about your health
- Come to clinic for two visits after you leave the hospital
- You will receive an eye examination before you finish the study.

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What risks should you consider?

The risks that might occur include an unexpected allergy to the IC14 study drug. You also might get a new infection, eye irritation or a low platelet count. Platelets are blood cells that help blood to clot to stop bleeding. If any of these happen, we will stop the study drug and you will be treated. If you have eye irritation you will see an eye specialist. You cannot take part in this study if you are pregnant or breastfeeding because it is not known if the IC14 study drug might have side effects for your unborn or nursing child.

Treatment and procedures in this research study may involve risks that are not known. You will be told if any new risks are identified during the study.

Why might you decide to join or not join the study?

Some reasons you might say "yes"

- Taking part in the study will help researchers and may help people with COVID-19 in the future.
- If you are given the IC14 antibody and it is effective, it may reduce how bad your symptoms are and how long they last.

Some reasons you might say "no"

- We do not know if the IC14 will make COVID-19 better or worse or have no effect.
- Being in this study means that you will be asked to provide blood samples and answer questions about how you feel.
- You do not have to be in this study to get care for COVID-19.
- There might be other COVID-19 studies that you would rather be in.

What can you do if you want more information?

The next pages of this document give you more information about the study, including:

- The risks (side effects) we know so far about the drug
- How we will protect your privacy
- Who will have access to the information we collect about you
- What will happen if you are injured because of the study procedures
- How we will use your information and samples in the future

Talk to the study team: We are here to help you understand the study. Ask us any questions you may have., We will give you time to think about whether or not you want to be in the study.

Talk to someone else: You may want to discuss the study with your family, friends, your regular doctor, or someone else. You can show them this document to help them discuss the study with you.

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ADDITIONAL STUDY INFORMATION

We are doing this study because we do not know if IC14 will be effective against COVID-19. If you receive IC14, we think that this might reduce your body's reaction to the virus. We do not know if the IC14 study drug will work. If you receive the saltwater solution, it will not help your COVID-19 illness.

The IC14 study drug is an experimental drug provided by a company named Implicit Bioscience, Ltd.

What will happen if you take part in this study?

Before you get the IC14 study drug (Screening):
We will review your medical record and collect information to check if you are eligible for the study. This will include information about your COVID-19 illness, medical history and medications

Study drug:

- You will receive the IC14 study drug or an identical appearing saltwater (saline) solution intravenously (IV) once a day for 4 days. The study treatment will take about two hours each day.
- A saltwater solution is being used as a placebo. A placebo is something that we know will have no effect on COVID-19. We use placebos in studies like this so we can learn whether the drug we are testing is effective.

  You will be assigned to receive the IC14 study drug or saltwater solution by a computer. You will have an equal chance of receiving either of these. You will not know which one you are taking, because they look the same.

  Your doctor and the research team will not know whether you are taking the IC14 study drug or the saltwater solution. The pharmacist knows what you are taking and can tell your doctors if they need to know.
- You also will receive a drug called remdesivir. This is a drug that is approved by the FDA for treatment of COVID-19 illness. Remdesivir is thought to work by reducing the spread of virus in your body. Remdesivir is given IV once a day for 5 days. We think remdesivir will not affect the IC14 study drug.

Samples:
Blood - While you are in the hospital, we will collect samples of blood (about 3 tablespoons) each day you receive the study drug. We will collect blood 3 more times after you start the study drug. The total amount of blood collected during the study is about one and a quarter cups or 20 tablespoons. These blood samples will be used to measure the amount of swelling and irritation in your body and to learn how the study drug works in your body. The results will not be shared with you.

Nose - A nose sample will be collected three times to check the amount of SARS-CoV-2 virus in your body. A cotton swab will be put into your nose and pushed gently to the back of your nose to get the sample.

If you have been discharged from the hospital, we will schedule you to come to our clinic 28 and 60 days after you began the study drug. A chest x-ray will be done and we will ask you some questions about how you are feeling.

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If you are transferred to another medical facility, we will contact you or your health care provider to find out how you are doing.

Chest x-ray - You will have a chest x-ray two times, when you come to clinic 28 days and 60 days after you began the study. The chest x-rays will be done to find out how COVID-19 has affected your lungs.

Questionnaire – You will complete a questionnaire about your health when you come back to clinic for your final visit 60 days after you began the study.

Medical information: While you are in the hospital we will gather information about your COVID illness from your medical record.

Eye Exam -After you leave the hospital, you will be scheduled for an eye exam by an eye specialist. The eye specialist will check for eye irritation. You will not have to pay for this exam.

Are there benefits to taking part in the study?

There may be no direct benefit for you for taking part in the study. Taking part in the study will help researchers and may help people with COVID-19 in the future. This study will also help researchers learn if the IC14 study drug reduces how bad your symptoms are and how long they last.

What side effects or risks might occur during the study?

Treatment and procedures in this research study may involve risks that are not known. You will be told if any new risks are identified during the study. You should talk to your doctor about any side effects you experience while taking part in the study.

Possible risks of the IC14 study drug

The IC14 study drug has some possible risks, including:

- allergy to the IC14 study drug
- worsening or new infections
- irritation in your eyes
- low platelet counts

Allergic reactions have been very rare in patients who have been treated with the IC14 study drug. There has not been any increase in new infections in patients who have received IC14. No patients have been diagnosed with eye problems related to IC14 study drug. No patients treated with IC14 study drug have had bleeding problems due to low platelet counts.

Previous studies of IC14 have enrolled 168 people, so there may be risks that are still unknown.

IC14 will not interfere with other drugs that you are getting for your COVID-19 illness.

If you develop worsening of your COVID-19 illness or experience side effects that your doctors think are due to the IC14 study drug, the study drug will be stopped.

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Possible risks of remdesivir (an anti-viral drug already approved for treatment of COVID-19)
The most frequent side effect of remdesivir is nausea (feeling sick to the stomach). The less common side effects are constipation, and headache. Some blood tests may become abnormal showing changes in liver or kidney function, increased blood sugar and low red blood cell count. A rare chance of allergic reactions is also possible.

Possible risks of saltwater solution (placebo, 0.9% w/v NaCl):
The risks of receiving saltwater solution are very low but could include pain where the needle is placed in your vein.

Possible risks of drawing blood for the study labs
You may have pain, redness, soreness, or bruising, from the blood draw. Rarely, some people faint when blood is drawn.

Possible risks of a chest x-ray
Any chest x-rays you have for research in this study will expose you to radiation. Everyone receives a small amount of radiation every day called "background radiation". This radiation is natural and comes from space, air, water, soil, and the food you eat. The chest x-rays in this study will give you a radiation dose that is less than the annual background radiation you receive normally. The risk to your health from this level of radiation exposure is too low to be detectable and may be nonexistent.

For women who are pregnant, breastfeeding or are able to have children:

You cannot take part in this study if you are pregnant or breastfeeding because the IC14 study drug might involve unexpected risks to an unborn or nursing child. A pregnancy test will be done before you start the study to make sure that you are not pregnant. We will tell you the result.

If you can become pregnant, you must agree to use birth control until the end of the study. You and your personal physician should discuss acceptable methods of birth control. If you become pregnant before the end of the study, you must contact the study doctor immediately. If you do become pregnant, we will contact you once the baby is born to ask you some questions about your baby's health.

How will my samples and information be used in the future?
Blood and nose samples and your medical information will be used in this study to learn more about IC14. We will ask you for permission to store your samples for future use by other researchers who may or may not be performing research related to this study. Your samples will be given a code, which means we will not share your name or any other personal information that would let the researchers know who you are. Your decision will not affect your ability to take part in this study.

Your stored coded samples also might be used to obtain knowledge about genetic information in relation to COVID 19 disease, related diseases, and/or the immune system. Genetic tests study an individual's inherited characteristics, found in DNA which is present in all of the cells of your body. DNA contains information needed to construct and operate the human body.

Where will my samples be stored: Your samples will be stored for future use in a laboratory at the University of Washington in Seattle, WA. Your samples will not be sold, but the information obtained from the research performed on your samples may lead to the development of commercial products. You will not receive any money from research using your stored samples and information.

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Research results: You will not receive the results of any tests performed on your samples or information that we collect during this study.

Commercial profit: The information and the specimens we collect as part of this research may be used for commercial profit. There is no plan to share this profit with you.

Benefits of storing leftover samples: There is no benefit to you from storing study samples and information. However, future researchers who have access to samples and information from you and many other people may be able to learn more about health and many different diseases.

Risks of storing leftover samples: There may be unknown risks from storing samples and information. For example, if future research involves genetic testing, your samples could be traced back to you because your genes are specific to you. We will make every attempt to protect your confidentiality and make sure your personal identity does not become known.

Who is funding this study?

The National Institute of Allergy and Infectious Diseases (NIAID) is funding this study. NIAID is part of the National Institutes of Health (NIH). The Implicit Bioscience Company makes IC14 and is providing IC14 for use in this study at no cost but is not providing any other funding for the study.

How many people will take part in this study?

About 350 people at about 15 major hospitals in the United States will take part in this study.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you, and you will not lose any of your regular health benefits. Leaving the study will not affect your medical care.

Can I stop being in the study?

Yes. You can decide to stop being in the study at any time. If you decide to stop, there is no penalty, and you will still be able to receive medical care. No one will be upset with you. It is important to tell the study team if you are thinking about stopping so any risks from the IC14 study drug can be evaluated, and the study team can discuss what follow-up care and testing could be most helpful for you. If you decide to stop taking the drug or leave the study, we will ask you if we can continue to follow you for up to 60 days as we had planned so we know how you are doing.

The study team may stop you from taking part in this study at any time if they believe it is in your best interest, if you are unable to complete required study treatments and examinations, or if the study is stopped.