Stellate Ganglion Blockade in COVID-19 Positive Patients

NCT04445337

01 Oct 2020

CONSENT FORM
Adult/LAR-Clinical Biomedical

Title of this Research Study
Stellate Ganglion Blockade for COVID-19 Positive Patients

Invitation and Summary

You are invited to be in this research study. Taking part in this research is voluntary. You do not have to take part. For the purposes of this document: "You" can refer to:

- Yourself
- The person for whom you are the Legally Authorized Representative (LAR)
- Your child under the age of 19.

"Organization" can refer to: University of Nebraska Medical Center (UNMC), Nebraska Medicine (NM), University of Nebraska at Omaha (UNO) or Children's Hospital & Medical Center (CH&MC).

Here is a summary of the purpose, methods, risks, benefits, and alternatives, to help you decide whether or not to take part in the research.

You are invited to be in this research study because you have COVID-19 and you are having breathing problems.

The purpose of this research study is to see whether a stellate ganglion block (SGB) is safe in patients with breathing problems due to COVID.

The SGB involves placing a small tube into the front of your neck, toward nerves at the back of your neck. This is done with the help of an x-ray machine or ultrasound device. The tube is left in place so you can get medication thru it for five days. Then the tube is taken out.

Researchers will collect information from your chart every day about your oxygen levels and breathing problems. Extra blood samples will be collected on days 1 and 5.
You will continue to get all the usual care for your COVID infection.
Risks include bruising, bleeding, swelling at the injection site, collapsed lung (pneumothorax), numbness of the arm or shoulder (brachial plexus block), numbness of the belly, hips or legs (spinal or epidural block), decreased heart rate, decreased rate of breathing (high spinal anesthetic), numbed or weakness in your hands or feet (nerve damage).

The medicine given through the tube might improve your breathing.

Instead of being in the research you can get the usual care for your COVID infection.

Why are you being asked to be in this research study?
You are being asked to participate in this study because you are COVID-19 positive, experiencing breathing related symptoms, and between the age of 40-85 years old. In COVID-19, research has shown our bodies response to the virus has an effect on the heart and lungs. The stellate ganglia is a part of a collection of nerves located near your neck just to the side of your windpipe.

What is the reason for doing this research study?
The reason this research is being done is to determine if SGB are safe and useful in treating COVID-19 positive patients who have heart and lung symptoms.

What will be done during this research study?
There will be up to 16 research participants enrolled in this study at UNMC/Nebraska Medicine.

You will be randomly assigned (like a flip of a coin) to one of two groups. An equal number of patients will be assigned to each research group.

If you are in the EXPERIMENTAL group, you will have the block placed in the ICU. The block will be placed on the left or right side of your neck under ultrasound or with fluoroscopy (a video x-ray). Ultrasound involves a probe on your neck and taking sound wave pictures of your body through your neck. The medication used for the block are clonidine 100 mcg, Decadron PF 5mg and 0.25% bupivacaine 5 mL. This medication will be administered once during the block. These medications are approved by the Food and Drug Administration (FDA). The intensive care nurse will monitor your vital signs during the block. You will be monitored every 15 minutes for 1 hour after the block is placed. The Acute Pain Service Team will follow you for in the ICU for 5 days. The catheter placed will be used to deliver 0.2% bupivacaine at 2mL/hour for 5 days. The small tube that will be placed will be removed after 5 days.

If you are in the STANDARD group, you will be treated as if you were not in the research. You will only have the lab studies and data collected from your electronic medical record (EMR). Labs will be done on the first day, third day and fifth day. We will collect about 1-2 teaspoons of blood.

All subjects will have data collected including: clinical outcomes (type of oxygen used, blood pressure and heart rate, chest x-ray and types of medications used.

All patients will have lab studies completed on Day 1, Day3, and Day 5. The sample(s) we collect will not be used for other research studies by us, or by any other investigator after this research is over.

Blood draws will be done on Day 1, Day 3, and Day 5. Each blood draw will be about 15 mL of blood or equal to about 1 tablespoon. Lab studies include; C-Reactive Protein (CRP), Cytokine Panel (Tumor Necrosis Factor-Alpha, Interleukin 6, Interleukin beta). These are commonly used blood test to measure the inflammatory markers in blood.

What are the possible risks of being in this research study?
Both EXPERIMENTAL and STANDARD Group:
For this study, we plan to take 15mL at each blood draw, which is equal to 1 tablespoon. You may feel a slight needle prick when we draw your blood. Some people may have a small bruise that will go away in a day or two. Sometimes, people feel light headed or faint. There is also a rare chance of infection with the blood draw.

EXPERIMENTAL Group Only:
Potential risks involved for the SGB block include: bruising, bleeding, swelling at the injection site, collapsed lung (pneumothorax), numbness of the arm or shoulder (brachial plexus block), numbness of the belly, hips or legs (spinal or epidural block), decreased heart rate, decreased rate of breathing (high spinal anesthetic), numbed or weakness in your hands or feet (nerve damage).

You could potentially have an allergic reaction to some of the medication that will be given with the stellate ganglion block. The medications being used are not a common cause of allergic reactions and are used routinely in patients who are very sick.

Risks of bupivacaine & Decadron medications include; allergic reaction, adrenal suppression (body aches, fatigue), increase of blood sugar levels. Risks of clonidine medication; allergic reaction, decreased blood pressure. There will be certain medications available that the doctor will administer in the event that you do have an allergic reaction. If your blood pressure does get low, the doctor will give you medication to help increase it.

You could also experience a higher level of sugar in your blood, which should go away on its own. The organ that sits on top of your kidneys (adrenal glands) may also

slow down, which could place you at greater risk of becoming sick. The doctor will have medication that he/she can give you if the organs that sit on your kidneys (adrenal glands) do slow down.

To reduce your risk the block will be placed using either real-time video images (fluoroscopy) or direct images using sound waves to produce pictures of the inside of the body (ultrasound). If fluoroscopy is used, there is a possible radiation risk of the procedure. You will be closely watched during the procedure using blood pressure, heart rate and oxygen monitors. Procedural and nursing staff will monitor you throughout the procedure and immediately after for 1 hour. You will remain on the heart monitor during the procedure and for 5 days after, while on the continuous local numbing medication.

If you experience any serious side effects such as severe low blood pressure, high spinal anesthetic, pneumothorax, bleeding, cardiac arrhythmia during the procedure, or allergic reaction develop, the procedure will be stopped and you will be withdrawn from the study.

What are the possible benefits to you?
You may not get any benefit from being in this research study.

If you are randomly assigned to the EXPERIMENTAL group there may be potential benefits of reducing injury or damage to your body, improving lung function, and reducing heart complications.

What are the possible benefits to other people?
If the results of this study are positive, future patients may benefit from the knowledge gained by this study.

What are the alternatives to being in this research study?
Instead of being in this research study, you can choose not to take part. If you do not participate in this study, the care you will receive in the intensive care unit will not change.

What will being in this research study cost you?
There is no cost to you to be in this research study.

Will you be paid for being in this research study?
You will not be paid to be in this research study.

Who is paying for this research?
UNMC Nebraska Neuroscience Alliance COVID-19 Rapid Response Grants gives us money to do this study.

What should you do if you are injured or have a medical problem during this research study?
Your health and safety is our main concern. If you are injured or have a medical problem because of this study call someone listed at the end of this consent form. You can get emergency medical treatment at Nebraska Medicine. You can also go to your doctor, the nearest emergency room or call 9-1-1.

We have no plans to pay for your treatment or give you any other money or compensation. Your insurance may pay. If they do not you will have to pay.

Signing this consent form does not mean you have given up any of your legal rights.

How will information about you be protected?
In the course of this research we may collect information about you. This can be things that could be used to find out who you are (like your name, phone number, birthdate, address). We call this "identifiable private information". We will keep this information as confidential as possible.
The information will not be used for other research by us, or by any other researcher.

Who can see information about you?
We also will get medical information about you (like medical record number, medical history, or the results of physical exams, blood tests, x-rays or other medical or research procedures). We call this "protected health information" or PHI. PHI is protected by a law called the HIPAA Privacy Rule. We will collect the smallest amount of PHI that we can. We will keep your PHI as confidential as possible.

By signing this consent form, you are letting us (the researchers listed on this consent form and other people involved in this research at the Organization) have access to your PHI. Your PHI will be used only for the purposes described in the section "What is the reason for doing this research study?"

You can change your mind and tell us to stop collecting your PHI for use in this research at any time by writing to the principal investigator. We can still use the PHI we have already collected. If you tell us to stop collecting your PHI, you will have to stop being in this research.

We may share your PHI with the following groups:

- The UNMC Institutional Review Board (IRB)
- Institutional officials designated by the UNMC IRB
- The HHS Office for Human Research Protections (OHRP)

We may also share your PHI with other groups listed below. The HIPAA Privacy Rule requires these groups to protect your PHI.

- The Food and Drug Administration (FDA)
- Your health insurance company

You are letting us use and share your research data for as long as the research is going on.

How will results of the research be made available to you during and after the study is finished?

In most cases, the results of the research can be made available to you when the study is completed, and all the results are analyzed by the investigator or the sponsor of the research. The information from this study may be published in scientific journals or presented at scientific meetings, but your identity will be kept strictly confidential.

If you want the results of the study, contact the Principal Investigator at the phone number given at the end of this form or by writing to the Principal Investigator at the following address:

Michael Lankhorst, MD
Department of Anesthesiology
University of Nebraska Medical Center
986890 Nebraska Medical Center
Omaha, NE 68198-6890
402-596-4200

What will happen if you decide not to be in this research study?

You can decide not to be in this research study. Deciding not to be in this research will not affect your medical care or your relationship with the investigator or the organization. Your doctor will still take care of you and you will not lose any benefits to which you are entitled.

What will happen if you decide to stop participating once you start?

You can stop being in this research (withdraw) at any time. Just call the researcher or

any research staff.
If you stop being in the research study it will not affect your care or your relationship with the investigator or the organization. You will not lose any benefits to which you are entitled.

Will you be given any important information during the study?
We will tell you right away if we get any new information that might make you change your mind about being in the study.

What should you do if you have any questions about the study?
We gave you a copy of *"What Do I Need to Know Before Being in a Research Study?"*

If you ever have any questions about this study, call the Principal Investigator or anyone else listed on this consent form.

What are your rights as a research participant?
You have rights as a research subject. These rights have been explained in this consent form and in The Rights of Research Subjects that you have been given. If you have any questions concerning your rights, or want to discuss problems, concerns, obtain information or offer input, or make a complaint about the research, you can contact any of the following:

- The investigator or other study personnel
- Institutional Review Board (IRB)
    - Telephone: (402) 559-6463
    - Email: IRBORA@unmc.edu
    - Mail: UNMC Institutional Review Board, 987830 Nebraska Medical Center, Omaha, NE 68198-7830
- Research Subject Advocate
    - Telephone: (402) 559-6941
    - Email: unmcrsa@unmc.edu

Documentation of informed consent
You are deciding whether to be in this research study. Signing means that:

- You have read and understood this consent form.
- You have had the consent form explained to you.
- You have been given a copy of The Rights of Research Subjects
- You have had your questions answered.
- You have decided to be in the research study.

- You have been told you can talk to one of the researchers listed below on this consent form if you have any questions during the study.
- You will be given a signed and dated copy of this consent form to keep.

Signature of Subject_____Date_____

Signature of LAR_____Date_____

My signature certifies that all the elements of informed consent described on this consent form have been explained fully to the subject/LAR. In my judgment, the subject/LAR possesses the legal capacity to give informed consent to participate in this research and is voluntarily and knowingly giving informed consent to participate.

Signature of Person Obtaining Consent_____
Date_____

Authorized Study Personnel
Principal
* Lankhorst, Michael
phone: 402-516-6336
alt #: 402-559-4081
degree: MD

Secondary
* Heiser, Nicholas
phone: 402-559-4175
alt #: 402-559-4081
degree: MD

* Kassel, Cale
phone: 402-559-4081
alt #: 402-559-4081
degree: MD

* Ladd, Marshall
phone: 402-559-4081
alt #: 402-550-4081
degree: DO

* Lisco, Steven
phone: 402-559-5780
alt #: 402-559-5780
degree: MD

* Nicholas, Thomas
alt #: 402-888-2140
degree: MD

Lead Coordinator

Hoffman, Julie (Julie)
phone: 402-559-8299
alt #: 402-559-8299
degree: RN BSN

Other Coordinator
Sindt, Lace
alt #: 402-559-4081
degree: RN

What Do I Need To Know Before Being In A Research Study?

You have been invited to be in a **research study**. Research studies are also called "clinical trials" or "protocols." **Research** is an organized plan designed to get new knowledge about a disease or the normal function of the body. The people who are in the research are called **research subjects**. The **investigator** is the person who is running the research study. You will get information from the investigator and the research team, and then you will be asked to give your **consent** to be in the research.

This sheet will help you think of questions to ask the investigator or his/her staff. You should know all these answers before you decide about being in the research.

What is the **purpose** of the research? Why is the investigator doing the research?

What are the **risks** of the research? What bad things could happen?

What are the possible **benefits** of the research? How might this help me?

How is this research different than the care or treatment I would get if I wasn t in the research? Are there other treatments I could get?

Does **everyone** in this research study get the same treatment?

Will being in the research **cost** me anything extra?

Do I have to be in this research study? Will the doctor still take care of me if I say **no**?

Can I **stop** being in the research once I ve started? How?

Who will look at my **records**?

How do I reach the investigator if I have more **questions**?

Who do I call if I have questions about being a **research subject**?

Make sure all your questions are answered before you decide whether or not to be in this research.

THE RIGHTS OF RESEARCH SUBJECTS
AS A RESEARCH SUBJECT YOU HAVE THE RIGHT

to be told everything you need to know about the research before you are asked to decide whether or not to take part in the research study. The research will be explained to you in a way that assures you understand enough to decide whether or not to take part.

to freely decide whether or not to take part in the research.

to decide not to be in the research, or to stop participating in the research at any time. This will not affect your medical care or your relationship with the investigator or the Nebraska Medical Center. Your doctor will still take care of you.

to ask questions about the research at any time. The investigator will answer your questions honestly and completely.

to know that your safety and welfare will always come first. The investigator will display the highest possible degree of skill and care throughout this research. Any risks or discomforts will be minimized as much as possible.

to privacy and confidentiality. The investigator will treat information about you carefully, and will respect your privacy.

... to keep all the legal rights you have now. You are not giving up any of your legal rights by taking part in this research study.

to be treated with dignity and respect at all times

The Institutional Review Board is responsible for assuring that your rights and welfare are protected. If you have any questions about your rights, contact the Institutional Review Board at (402) 559-6463.