Columbia University Consent Form

Protocol Information

Attached to Protocol: IRB-AAAS8305
Principal Investigator: Sachin Agarwal (sa2512)
IRB Protocol Title: Stellate Ganglion Blockade to Reduce PTSD Symptoms in Cardiac Arrest Survivors: A Pilot Randomized Clinical Trial

General Information

Consent Number: CF-AACH3600
Participation Duration: 3 Months
Anticipated Number of Subjects: 15

Research Purpose: The purpose of this study is to help determine if performing a stellate ganglion block (SGB) represents a promising intervention for post-traumatic stress disorder(PTSD)for early PTSD in Cardiac Arrest survivors. A stellate ganglion block (SGB) is a procedure that consists of an injection of local numbing medicine to block the nerves located on either side of the voice box in the neck.

Contacts

Contact	Title	Contact Information
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Information on Research

The purpose of this study is to help determine if performing a stellate ganglion block (SGB) represents a promising intervention for post-traumatic stress disorder (PTSD)for early PTSD in Cardiac Arrest survivors. A stellate ganglion block (SGB) is a procedure that consist of an injection of local numbing medicine to block the nerves located on either side of the voice box in the neck. This information may lead to the development of improved treatments and

rehabilitation interventions which specifically address the needs of cardiac arrest patients.

Your participation in this study is voluntary.

If you agree to participate in this study, you will be randomized to a stellate ganglion block (SGB) intervention or placebo control (water injection) in an inpatient monitored setting. A stellate ganglion block (SGB) is an injection of local anesthetic (numbing medicine) to block the nerves located on either side of the voice box in the neck. We will ask you to complete a series of questionnaires after the procedure and we will follow up with you at 1,4 and 12-weeks post-procedure. The study follow ups will take approximately 1 hour.

The time frame for the study is 12 weeks.

The detailed information in sections “Information on Research” below gives full instructions.

The reasons you might not want to participate in this study is that you may feel discomfort during the procedure. Also there’s a possibility of complications such as hoarseness, difficulty swallowing (dysphagia), inadvertent temporary block of nerves innervating the larynx and may result in a temporary hoarse voice or a sensation that there is something in the back of the throat, and can last up to 10 hours following injection. Although rare, more serious complications include seizures from inadvertent injection of local anesthetic into a blood vessel, or a hematoma or localized collection of blood that could compromise the airway and result in death. There’s also a possibility of a loss of confidentiality. The study team plans to protect your confidentiality. Their plans for keeping your information private are described in the “What about your privacy?” section of this consent form.

All the known risks are listed in section “Risks”.

Are there any benefits? There is no direct benefit to participation except that participants in the intervention arm may experience reduction in their anxiety symptoms associated with PTSD.

You can choose to withdraw at any time during the study. If you choose not to volunteer, you will not lose any services, benefits, or rights you would normally have.

If you are interested in learning more about this study, please read the details below.

The purpose of this form is to give you information to help you decide if you want to take part in a research study. This consent form includes information about:

- why the study is being done;
- the things that you will be asked to do if you are in the study; - any known risks involved;
- any potential benefit;
- options, other than taking part in this study, that you have.

A member of the research staff will discuss the study with you. If at any time, you have questions about the study, please ask a member of the study team. Take all the time you need to decide whether you want to take part in this study.

Study Purpose

You are being asked to take part in this study because you have suffered a cardiac arrest, are enrolled in the Positive and Negative Psychological Predictors of Long-Term Recovery after Cardiac Arrest study (PACE study, IRB # AAAT4053), gave permission to be contacted for future research opportunities and have been identified to have high levels of post-traumatic stress disorder symptoms. About 15 people are expected to be enrolled in this study at Columbia University Medical Center.

Cardiac Arrest is often associated with permanent physical, intellectual and emotional problems which affect basic activities of daily living and long term quality of life. While most survivors retain their learning/thinking function and physical independence, many face psychological consequences. In particular, many describe the Cardiac Arrest experience as traumatic, and up to 1 in 3 survivors develop posttraumatic stress disorder (PTSD).

The purpose of this study is to help determine if performing a stellate ganglion block (SGB) represents a promising intervention for post-traumatic stress disorder (PTSD) for early PTSD in Cardiac Arrest survivors. A stellate ganglion block (SGB) is a procedure that consists of an injection of local numbing medicine to block the nerves located on either side of the voice box in the neck. This information may lead to the development of improved treatments and rehabilitation interventions which specifically address the needs of cardiac arrest patients.

The stellate ganglion block (SGB) has shown to be an effective therapy helping with the excess activity of your nervous system that presents as a decrease response to relaxation. Right-sided stellate ganglion block (SGB) is a therapy that can be used to prevent sustained PTSD symptoms, as SGB can affect both the central autonomic network (which is an important part of the way the brain controls responses essential for survival) as well as the cardiovascular system, which are central systems responsible for PTSD and anxiety.

Study Procedures

If you decide to participate in the study, you will be randomly assigned to either the stellate ganglion block (SGB) intervention arm or the placebo control (10 cc of preservative-free normal saline) arm. You are twice as likely to be assigned to the SGB intervention arm. A SGB is an injection of local anesthetic (numbing medication) to block the nerves located on either side of the voice box in the neck. An injection at these nerves are usually done in standard of care to reduce symptoms such as pain, swelling, color, sweating changes in the upper extremity and to improve mobility. Patients, and assessors (the coordinators administering the questionnaires) will not know the group assignment. The doctor performing the procedure either the SGB intervention arm or the placebo control will know the group assignment. The procedure will be performed once before discharge. Before the procedure, you will complete a 30-minute educational session with the study PI and a study team member focused on the procedure, cardiac arrest, various health behaviors and safety procedures.

Before you are discharged from the hospital, you will also be asked to complete a series of questionnaires.

Additionally, you will be asked to participate in a 1-hour telephone follow-up at 1, 4 and 12-weeks post-procedure in order to evaluate the long-term outcome of your condition and assess any adverse events you have experienced. This interview will include questions regarding your current health and a variety of tests to assess your psychological state (e.g. cardiac anxiety, PTSD, depression).

Information regarding your condition and medical treatment will be recorded from the medical record during your stay

in the hospital.

Storage of the data we collect for this study will be on a web-based data collection system called REDCap, which has been deemed safe and confidential by the CUMC IT department. Only members of the study team will have access to this database.

Risks

There may be risks or discomforts if you take part in this study. These include: discomfort during the procedure, mild complications such as abnormal voice changes (hoarseness), difficulty swallowing (dysphagia) may occur in 13.5% of the cases, unintentional temporary block of the voice box (larynx) nerves may occur in up to 15% of cases and may result in a temporary hoarse voice or a sensation that there is something in the back of the throat, and can last up to 10 hours following injection. Although rare, more serious complications include seizure from the unintentional injection of the medication into a blood vessel, or a hematoma (localized collection of blood) that could compromise the airway and result in death.

If you experience significant and increasing pain in the neck—more than just a mild pain from the needle—we will immediately seek medical attention, as it could represent a hemorrhage in the neck. Although highly unlikely, collapsed of one of the lungs (pneumothorax) has been reported with the procedure. It is acceptable for you to talk during the injection. You should let the study doctor know if you have any new or strange sensations during the procedure, including tingling of the skin or mouth, ringing in the ears, or just feeling odd.

There’s also a risk of a loss of confidentiality. Loss of confidentiality includes having your personal information shared with someone who is not on the study team and was not supposed to see or know about your information. The study team plans to protect your confidentiality. Their plans for keeping your information private are described in the "confidentiality"; section of this consent form.

Benefits

There is no direct benefit to participation except that participants in the intervention arm may experience reduction in their anxiety symptoms associated with PTSD. Patients may have some variation of feeling “relaxed, light, and calm.” Additionally, the pilot study will contribute to scientific knowledge about stress, emotion, and autonomic nervous system of the human body that may help others in the future.

Alternative Procedures

You may choose not to take part in this research study.

Confidentiality

Any information collected during this study that can identify you by name will be kept confidential. We will do everything we can to keep your data secure, however, complete confidentiality cannot be promised. Despite all of our efforts, unanticipated problems such as a stolen computer may occur, although it is highly unlikely.

Access to your health information is required to be part of this study. If you choose to take part in this study, you are giving us the authorization (i.e. your permission) to use the protected health information and information collected during the research that can identify you. The health information that we may collect and use for this research may include medical history that may be considered sensitive.

Your participation in this research study will be documented in your electronic medical record. This record can be viewed by authorized personnel from Columbia University Irving Medical Center, Weill Cornell Medical Center and NewYork-Presbyterian Hospital and its affiliated institutions, because these institutions share the electronic medical record system. Study monitors and others who provide oversight of the study may also need to access this record.

Information about you may be obtained from any hospital, doctor, and other health care provider involved in your care that is needed for this research purpose.

Any research information that is shared with people outside of Columbia University Medical Center and NewYork-Presbyterian Hospital will not include your name, address, telephone number or any other direct identifier unless disclosure of the information is required by law or you have authorized the disclosure.

Your data, questionnaire responses, and health information will be assigned a code number, and separated from your name or any other information that could identify you. The research file that links your name to the code number will be kept in a Columbia IT password-protected computer and only the investigator and authorized study staff will have access to the file.

The following individuals and/or agencies will be able to look at, copy, use, and share your research information:

- The investigator and Columbia University Medical Center study staff and other medical professionals who may be evaluating the study.
- Authorities from Columbia University including the Institutional Review Board ('IRB')
- The Office of Human Research Protections ('OHRP')
- The sponsors of this study, the National Institute of Health (NIH), including persons or organizations working with or owned by the sponsor
- Other government regulatory agencies

Your authorization to use and share your health information does not have an expiration (ending) date.

Once your health information has been disclosed to a third party, federal privacy laws may no longer protect it from further disclosure.

You may change your mind and revoke (take back) this consent and authorization at any time and for any reason. To revoke this consent and authorization, you must contact the Principal Investigator, Dr. Sachin Agarwal.

However, if you revoke your consent and authorization, you will not be allowed to continue taking part in the Research. Also, even if you revoke this consent and authorization, the researchers may continue to use and disclose the information they have already collected.

Certificate of Confidentiality

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

Please note, by consenting to participate in this study (the Stellate Ganglion Block study), you are giving permission to have the data collected as part of your participation in the PACE study (IRB# AAAT4053) linked to the data collected as part of the SGB study.

Research Related Injuries

Taking part in this research study may result in injury or harm to you. In the event of an injury resulting from your participation in this study, you should seek appropriate medical care and inform the study doctor. In the event of an emergency you should go to an emergency room.

If you are injured or harmed as a result of participating in the study and receive medical care through the NewYork-Presbyterian Hospital (NYPH), a Columbia doctor, or any other health provider, you will be sent a bill for whatever medical care you receive. All or part of your bill may be paid by your health insurance.

Compensation

You will receive a $50 PayCard at the completion of the first 60-minute in-clinic visit. Then, an additional PayCard will be mailed to you within 4 weeks of your in-clinic visit. You will be compensated $25 for completing follow-up phone call #1, $50 for completing follow-up phone call #2 and $50 for completing follow-up phone call #3.

Altogether, you may receive up to $175 for participating in this study. Please note that the second PayCard (which will be mailed to you) will not immediately have funds on it; the study team will first need to confirm you have received it and will then submit for your compensation. It is important not to activate the card until the study team has notified you that it has been funded. The study team will contact you each time additional funds are loaded onto this card. Please allow several weeks for funds to be added to your PayCard, and please inform us immediately if you lose your card. We are not responsible for the PayCard after delivery, but can issue you a new PayCard for future deposits should you lose access to your card.

Additional Costs

There are no costs to you for taking part in this study.

Voluntary Participation

Taking part in this study is your choice. You can decide not to take part in or stop being in the study at any time. Your choice will not affect the treatment you receive from doctors and staff at Columbia University Medical Center and New York Presbyterian Hospital.

Additional Information

If you have any questions or are hurt while taking part in this research study, you should contact Dr. Sachin Agarwal at 212-305-7236.

If you have any questions about your rights as a subject, you may contact the Institutional Review Board by mail, telephone, or email at:

Institutional Review Board
Columbia University Medical Center

154 Haven Avenue, 1st Floor
New York, NY 10032
Telephone: (212) 305-5883
Email: irboffice@columbia.edu

More information about taking part in a research study can be found on the Columbia University IRB website at: http://www.cumc.columbia.edu/dept/irb.

Statement of Consent

I have read the consent form and talked about this research study, including the purpose, procedures, risks, benefits and alternatives with the researcher. Any questions I had were answered to my satisfaction. I am aware that by signing below, I am agreeing to take part in this research study and that I can stop being in the study at any time. I am not waiving (giving up) any of my legal rights by signing this consent form. I will be given a copy of this consent form to keep for my records.

Signatures

Participant Signature Lines

Study Participant
Print Name _____ Signature _____
Date & Time _____

Research Signature Lines

Person Obtaining Consent
Print Name _____ Signature _____
Date & Time _____