

ADVANCED PAIN CENTERS AND ALEXIAN BROTHERS HOSPITAL NETWORK

Consent for Participation in Research

A Pilot Study of Stellate Ganglion Block as a Method to Provide Relief from Hot Flashes in Women Who Are Breast Cancer Survivors.

Why am I being asked?

You are being asked to be a subject in a research study about the use of stellate ganglion block to reduce the number and severity of hot flashes in women who have hot flashes as a result of therapy for breast cancer. The study is being conducted by Eugene Lipov, MD and Dr. Jaydeep Joshi, M.D. at the offices of Advanced Pain Centers. You have been asked to participate in the research because you have been treated for breast cancer and are currently experiencing severe hot flashes as a result of your therapy and may be eligible to participate. We ask that you read this form and ask any questions you may have before agreeing to be in the research.

Your participation in this research is voluntary. Your decision whether or not to participate will not affect your current or future relations with Dr. Lipov, Dr. Jaydeep Joshi or with Alexian Brothers Hospital Network. If you decide to participate, you are free to withdraw at any time without affecting that relationship.

Why is this research being done?

Researchers have reported that women who are breast cancer survivors may experience hot flashes that are more frequent, more severe and of greater duration than other women. Hot flashes can have a significant impact on daily living, disrupt sleep, and lead to fatigue and irritability during the day. Hot flashes are the most common reason that women seek hormonal therapy. However, for breast cancer survivors this is rarely an option.

There are several other therapies using drugs, herbal preparations and lifestyle interventions that have had varying degrees of success in treating hot flashes. The procedure known as stellate ganglion block has been successful in treating other conditions, including excessive sweating. Its use for hot flashes was suggested by a similarity in these conditions and the similar activity in the nervous system.

What is the purpose of this research?

The purpose of this research is to study the use of the stellate ganglion block procedure to provide relief from severe hot flashes. A total of 12 patients have received 24 procedures performed by the investigator of this study to relieve symptoms of women who experience moderate to severe hot flashes due to menopause (change of life). Many of these women experienced relief from their hot flashes after the procedure was performed, and we now want to evaluate this treatment in a more organized, scientific way. The use of stellate ganglion block is approved for various pain conditions, but it is experimental in the relief of symptoms for hot flashes.

What procedures are involved?

Approximately 10 women may be involved in this research.

If you agree to be in this research, we ask you to do the following things:

You will be interviewed to determine if you are a candidate for the study. If you are accepted into the study and you sign this consent form, you will start the study by providing information about yourself and your medical history. You will also be asked to complete some forms that will assist us in the evaluation of the results of the therapy. These forms are:

- The Center for Epidemiologic Studies Depression Scale (CES-D) – 20 questions requiring you to provide a single choice for each.
- The Functional Assessment of Cancer Therapy – Breast (FACT-B) – 37 questions requiring you to provide a single choice for each.
- The Pittsburgh Sleep Quality Index (PSQI) – 9 questions, one with 10 parts, requiring you to provide a single choice for each.

Each form should take you 10 to 15 minutes to complete.

One week before having the procedure you will start keeping a diary of your hot flashes, recording the number and severity using a scale that will be provided to you. You will also record any comments you think will help in the evaluation of the number of hot flashes and the severity of hot flashes you experience each day.

Next, you will come to the office for the stellate ganglion block procedure. After preparation, the right side of your neck will be injected, using a local anesthetic to numb the area first. If you prefer, sedation is available as well. A liquid, known as a contrast agent, is injected to help visualize the area where the blocking agent will be injected and fluoroscopy (X-ray) is used to show the spot for injection. Marcaine, a commonly used anesthetic drug, is injected at this spot, into the neck on the right side. This procedure will take a few minutes. After it is completed, you will stay in the office for about half an hour for observation. Your blood pressure will be checked. A highly likely side effect of the procedure that will be watched for is known as Horner's syndrome. This includes a drooping of the right eyelid, redness in the eye and sweating on the right side of your face. This reaction will last about eight (8) hours.

In one week you will return to the office for evaluation. During this week you will continue to keep the diary of hot flashes each day. You will be asked to complete the other forms mentioned above to evaluate the results of the procedure during this visit as well. You will complete these forms one week before the procedure, one week after the procedure, two weeks after the procedure, and one, three and six months after the procedure. You will return to the office in one month, six months, and finally one year after the procedure for additional evaluation. After the first week you will record in the diary one day a week during the one year evaluation. If you report to the office that the hot flashes are getting more severe and frequent, this is an indication that the effect of the procedure is wearing off. We can repeat the block procedure if hot flashes return. These can be repeated two or more weeks apart. The maximum amount of blocks that can be done is three. Frequency depends on patient symptoms. With repeated blocks the chance of a side effect occurrence increases with each additional injection.

What are the potential risks and discomforts?

The research has several risks:

Stellate ganglion block carries the risk of infection (1 in 3000-4000), bleeding (1 in 3000-4000), seizures (1 in 2000), spinal cord trauma (extremely rare), which could be reversible, or irreversible if the needle is placed in the spinal canal. However these can be effectively minimized with the use of contrast dye and fluoroscopic guidance. Other potential, but rare risks of the procedure are:

Related to misplacement of the needle:

- Hematoma (blood clot) from injury to the veins

 - Carotid artery injury

 - Internal jugular vein injury

- Nerve injury

 - Injury could occur to the nerves that run down the arm or into the face. You might feel numbness or a burning sensation. You might experience a loss of function or in rare instances paralysis.

- Lung injury

 - Pneumothorax (air in the lung)

 - Hemothorax (blood in the lung)

- Other

 - Esophageal perforations

Related to spread of local anesthetic

- Intravascular injection

 - Carotid artery

 - Vertebral artery

 - Internal jugular vein

- Neuraxial/brachial plexus spread (this involves possible spread of the local anesthetic into the lower neck or the back or an effect on the nerves supplying the arm, forearm, or hands.

 - Epidural (injection into the dura mater that covers the spine)

 - Intrathecal (injection into the innermost membrane that surrounds the central nervous system)

 - Numbness or injury of the brachial plexus (the spinal nerves that run through the arm, forearm and hand); intraneural injection

- Local spread

 - Hoarseness

 - Elevated hemidiaphragm that may affect breathing

Infection (esophageal perforation is a predisposing factor)

- Soft tissue (abscess)

- Neuraxial (meningitis)

There is also the risk associated with exposure to radiation during the fluoroscopy. As used in this procedure, fluoroscopy gives a dose of X-rays that is less than 5% the amount provided during a normal chest X-ray. Blood pressure instability can also occur, meaning the blood pressure can go up or down. There is also the risk of an allergic reaction to the contrast dye used during the fluoroscopy. There may be other risks from the procedure that are currently unknown.

Are there benefits to taking part in the research?

Based on experience with this procedure in other patients treated for pain relief or related conditions, researchers believe it may be of benefit to subjects with your condition. Of course, because individuals respond differently to therapy, no one can know in advance if it will be helpful in your particular case. The potential benefits may include: reduction in the severity and frequency of hot flashes, and an improvement in your overall feeling of well being and ability to perform the functions of daily living.

What other options are there?

Alternative treatments that might benefit you would be hormone replacement therapy, selective serotonin reuptake inhibitors, commonly known as anti-depressant drugs, or other alternative therapies such as black cohosh or vitamin E.

Will I be told about new information that may affect my decision to participate?

During the course of the study, you will be informed of any significant new findings (either good or bad), such as changes in the risks or benefits resulting from participation in the research or new alternatives to participation that might cause you to change your mind about continuing in the study. If new information is provided to you, your consent to continue participating in this study will be re-obtained.

What about privacy and confidentiality?

The only people who will know that you are a research subject are members of the research team, and, if appropriate, your physicians and nurses. No information about you, or provided by you during the research, will be disclosed to others without your written permission, except: if necessary to protect your rights or welfare (for example, if you are injured and need emergency care or when the ABHN Institutional Review Board monitors the research or consent process); or if required by law.

When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity.

Authorized representatives of the Food and Drug Administration (FDA) may need to review records of individual subjects. As a result, they may see your name; but they are bound by rules of confidentiality not to reveal your identity to others.

What if labs, radiology, prescriptions or other diagnostic tests are necessary?

In the event that the researcher feels it is medically necessary for a lab, radiology, diagnostic test or prescription to be ordered, you or your third party payer, if any, will be responsible for payment of these services. These services are rendered outside of Advanced Pain Centers' offices and are not covered under this research study.

What if I am injured as a result of my participation?

In the event of injury related to this research, treatment will be available through the Alexian Brothers Medical Center or St. Alexius Medical Center. However, you or your third party payer, if any, will be responsible for payment of this treatment. There is no compensation and/or payment for such medical treatment from the Medical Center for such injury except as may be required by law.

If you feel you have been injured, you may contact the researcher, Dr. Eugene Lipov or Dr. Jaydeep Joshi at 847-608-6620.

What are the costs for participating in this research?

Neither you nor your insurance company will be billed for your participation in this research.

Will I be reimbursed for any of my expenses or paid for my participation in this research?

You will not be paid for your participation in this research.

Can I withdraw or be removed from the study?

Your participation in this research is **VOLUNTARY**. If you choose not to participate, that will not affect your relationship with the investigator or the medical centers or your right to health care or other services to which you are otherwise entitled. If you decide to participate, you are free to withdraw your consent and discontinue participation at any time without affecting your future care.

The investigator may withdraw you from participating in this research without your consent if circumstances arise which warrant doing so. The investigator, Dr. Eugene Lipov or Dr. Jaydeep Joshi, will make the decision and let you know if it is not possible for you to continue. The decision may be made either to protect your health and safety, because it is part of the research plan that people who develop certain conditions may not continue to participate, or because the sponsor of the research has decided to stop the research.

Who should I contact if I have questions?

The researchers conducting this study are Dr. Eugene Lipov and Dr. Jaydeep Joshi. You may ask any questions you have now. If you have questions later, you may contact the researchers at: 847-608-6620.

What are my rights as a research subject?

If you have any questions about your rights as a research subject, you may call the Co-Chairperson of the Alexian Brothers Hospital Network Institutional Review Board, Joan Hardman, RPh, at 847-981-3609.

Remember: Your participation in this research is voluntary. Your decision whether or not to participate will not affect your current or future relations with the medical centers or the

Authorization for Use and Disclosure of Health Information for Research Purposes

1. You agree to permit Eugene Lipov, MD and Dr. Jaydeep Joshi and their staff, (“Researchers”) conducting the research study “A Pilot Study of Stellate Ganglion Block as a Method to Provide Relief from Hot Flashes in Women Who Are Breast Cancer Survivors,” to use and disclose health information about you.

2. When we talk about health information about you to be used and disclosed, it includes all information about you collected during the research study for research purposes and the health information about you in medical records that is related to the research study. For example, it would include laboratory tests such as your blood counts and tests to measure the function of your liver and kidneys, x-rays or scans, and the following health information and tests: measures of quality of life, quality of sleep, frequency and severity of hot flashes, and emotional well being.

3. Health information about you may also be disclosed to and reviewed by the Alexian Brothers Hospital Network Institutional Review Board, and representatives of government agencies, including the Food and Drug Administration (FDA) for the purpose of assuring the safe conduct of the research study.

If health information about you is required, the reviewers may need access to your entire medical record.

4. Health information about you may also be used to create information that does not identify you. The deidentified data may be used and released by Researchers, including use for other research purposes.

5. This health information about you may be further disclosed by the Receivers of the information. If disclosed by them, the information may no longer be covered by federal or state privacy regulations.

6. Information collected about you for purposes of this research study may be kept in a research study record separate from your medical records. You will not be able to obtain your research study record until the end of the study.

7. In order to participate in this research study, you must sign this Authorization. However, you cannot be denied medical treatment because you did not sign this Authorization.

8. This Authorization has no expiration date.

9. You have the right to revoke this Authorization at any time by a written notification to the Researchers’ Privacy Contact: Jo Anne Burkhardt, Privacy Officer at 2260 W. Higgins Road, Suite 101, Hoffman Estates, IL. 60195. If you revoke this Authorization, you will no longer be allowed to participate in the research. Also, even if you revoke this Authorization, the Researchers may still use and disclose the health information that they have already obtained as necessary to maintain the reliability of the research.

10. You will receive a signed copy of this form.

Signature of Research Participant

Date

Print Name of Research Participant

For Personal Representative of the Research Participant (if applicable)

Print Name of Personal Representative: _____

Describe Personal Representative Relationship:

(e.g., parent, guardian, power of attorney, etc.) I certify that I have the legal authority under applicable law to make this Authorization on behalf of the Research Participant identified above.

Signature of Personal Representative

Date