Version Date: 1 October 2018

CONSENT FOR RESEARCH
Penn State College of Medicine
The Milton S. Hershey Medical Center

Title of Project: Effectiveness of Sphenopalatine ganglion block for Post-Dural Puncture Headache; A pilot study

Principal Investigator: Verghese Cherian, MD

Address: Department of Anesthesiology & Perioperative Medicine, H187
Penn State Health Milton S. Hershey Medical Center
500 University Dr.
Hershey, PA 17033

Telephone Numbers: Weekdays: 8:00 a.m. to 5:00 p.m. (717) 531-6926.
After hours, call (717) 531-8521. Ask for the Anesthesiology Attending doctor on 24-hour call.

Subject's Printed Name: _____

We are asking you to be in a research study.

Whether or not you take part is up to you. You can choose not to take part. You can agree to take part and later change your mind. Your decision will not be held against you.

This form gives you information about the research. Please ask questions about anything that is unclear to you and take your time to make your choice.

1. Why is this research study being done?

Lumbar puncture (needle into your backbone) is a commonly performed diagnostic procedure in medicine and also for anesthesia. Inadvertent puncture of the coverings of the spinal cord can occur during epidural (space around the covering of the spinal cord) anesthesia and placement of an epidural catheter. Headache after a dural (covering of the spinal cord) puncture is not uncommon and can be excruciatingly painful. Most often it is self-limited and the pain subsides within 1-2 weeks. However, if left untreated, it can at times lead to considerable problems including chronic neck and back pain, bleeding under the covering of the brain, and seizures.
The sphenopalatine ganglion (SPG) is a cluster of nerves found at the back of your nose. A sphenopalatine ganglion (SPG) block (numbing the nerves with local anesthetic medicine, such as Lidocaine) is used to treat head and facial pain. SPG block can be achieved by placing cotton swabs soaked with numbing medication (lidocaineJelly) into the back of the nose.

This research is being done to study the effectiveness of sphenopalatine ganglion block in the treatment of headache following dural puncture.

We are asking you to be in this research because
- You have been diagnosed with post-dural puncture headache

- You are considered medically suitable for sphenopalatine ganglion block for the treatment of post-dural puncture headache

Approximately 30 people will take part in this research study at the Hershey Medical Center.

2. What will happen in this research study?

Study intervention

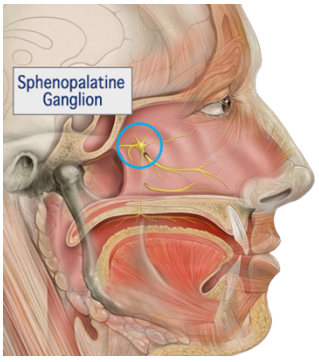
If you agree to participate in the study, you will first review and sign this consent document. You will be given a copy of the signed consent for your records.

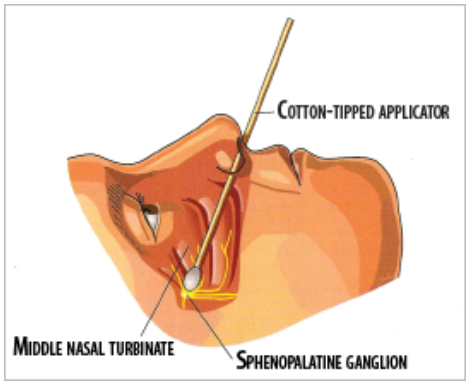
The following will be done for the research prior to performing sphenopalatine block:

- A urine test to rule out pregnancy will be done for non-post-partum women participants.
- The worst pain score (on a scale 0-10) that you experience while sitting at the edge of the bed for 5 minutes, will be recorded. It will be graded as 10 if you cannot sit up.
- An intravenous (IV) catheter will be placed in your arm and an infusion of IV fluid will be started, if you don't already have one. Infusion of IV fluid is part of standard care and not for this research.
- Continuous monitoring of your heart's electrical activity using and electrocardiogram (ECG), the amount of oxygen carried in the body using a pulse-oximeter and non-invasive blood pressure monitoring will be established and your skin temperature will be recorded. All these monitoring is also standard of care. However, the data from these monitors will be used for research.
- You will be asked to lie flat on your back (supine position) with your neck slightly extended.

Sphenopalatine block

Anatomy: The Sphenopalatine ganglion is a small, collection of nerves located at the back of the nose, just under the inner lining (mucosa) of both the nostrils. Please see the image illustration below.





Lidocaine 2% jelly is dispensed in a 6ml syringe. The investigator will squirt 1ml of this medication on a cotton tipped plastic applicator. One such applicator will be gently inserted into each nostril, along the floor of the nose. Slight rotatory motion of the stick will be used to insert it as far as it goes with the intention to reach the nasopharyngeal wall (posterior wall of the nose). At that position the swab sticks (one in each nostril) will be left undisturbed for 5 minutes. The swabs will be taken out and this will be repeated twice more, using fresh applicators and 1ml of 2% lidocaine jelly on each applicator. The whole procedure would take about 30 minutes.

After the procedure you will be asked if you are comfortable and if you have any side effects. You will be asked to sit up with your legs dangling over the side of the bed. If you can sit for about 15 minutes without pain and your blood pressure is stable, you will be asked to stand and walk. At any stage, if the headache returns or you cannot sit up or stand for any other reason, you will be made to lie down.

If the headache goes away, you will be discharged to go home. You will be encouraged to drink plenty of fluids and caffeinated drinks and get as much bed rest as possible for the next 3 days.

On Day 1, 2, and 7 after the procedure, one of the investigators will call you to ask a set of questions about the headache and any side effects. A follow up phone call, at 1 month after the SP ganglion block, will be made to ask for any residual headache or other symptoms and your satisfaction with the management.

If your headache does not get relieved or recurs, you will have the option to undergo an epidural blood patch. The epidural blood patch will be performed as standard care (not part of this research).

We will also collect information (demographic details, past medical history, details of the procedure that led to the current headache) from your medical record for this research.

3. What are the risks and possible discomforts from being in this research study?

This study may involve risks that are currently unforeseeable.

The possible side effects of the SPG block are

- allergic reaction to lidocaine
- mild pressure or a feeling like you have to sneeze
- brief mild discomfort or irritation in the nose
- brief or quick burning sensation
- bad taste in your mouth as some of the lidocaine may drip down into your mouth
- tearing and a brief temperature change
- temporary numbness in the throat related to a small amount of the lidocaine dripping into your mouth (This numbness should not last more than a few hours. During this time, it is safest if you avoid eating or drinking anything to avoid the risk of choking.)
- nasal bleeding or infection have been reported, in some cases may be severe bleeding
- rarely, a temporary increase in pain has been reported
- may have temporary or no relief from procedure

If you are breast-feeding your baby, the amount of lidocaine that may be absorbed into the blood stream, from this procedure, and excreted in the breast milk is minimal, and studies have shown that it is safe to continue breast-feeding. However, we would advise you NOT to breast feed your baby for 4h and to express the next breast milk and discard.

There is a risk of loss of confidentiality if your information or your identity is obtained by someone other than the investigators, but precautions will be taken to prevent this from happening. The confidentiality of your electronic data created by you or by the researchers will be maintained to the degree permitted by the technology used. Absolute confidentiality cannot be guaranteed.

4. What are the possible benefits from being in this research study?

4a. What are the possible benefits to me?

There is no guarantee that you will benefit from this research. The possible benefits you may experience from this research study include relief of your post-dural puncture headache.

4b. What are the possible benefits to others?
The result of this study may guide the future treatment of post-dural puncture headache.

5. What other options are available instead of being in this research study?
You do not have to take part in this study to be treated for your condition. Instead of participating in this research, you could:

- Receive available treatments, including an epidural blood patch. An epidural blood patch is done by inserting a needle into your back similar to the one you had, and try to locate the epidural space (space around the covering of the spinal cord). Then 20 ml (4 teaspoon) of your blood will be taken from one of your veins and injected through the needle in your back. While injecting the blood you may feel a sensation of pressure or pain. The risks of epidural blood patch are
    - - inadvertent dural puncture
    - -inflammation or infection due to the injected blood
    - -it may not help the headache or may help for a short time and recur
- Be part of a different research study, if one is available.

Before you decide if you want to be in this research, we will discuss the other choices that are available to you. We will tell you about the possible benefits and risks of these choices.

The therapy offered in this research is available to you without taking part in this research study, although currently the first line of treatment for PDPH is an epidural blood patch.

6. How long will I take part in this research study?
If you agree to take part, it will take about two to three hours to do the SP ganglion block and to observe you before discharge. On day one, two and seven, one of the investigators will be contacting you by phone, once a day, to enquire about your headache and any other side-effects you might have. One of the investigators will call you by phone about 1 month later to ask you if you have any residual headache, backache, neck spasms or any other problems associated with this block.

7. How will you protect my privacy and confidentiality if I decide to take part in this research study?

7a. What happens to the information collected for the research?

Efforts will be made to limit the use and sharing of your personal research information. In our research files at The Milton S. Hershey Medical Center (HMC) and Penn State College of Medicine (PSU) we will include these identifiers: your name, address, dates (e.g. date of birth, dates of treatment), telephone number, medical record number, and a study ID code.

- A list that matches your name with your code number will be kept in a locked file in Dr. Verghese Cherian's office.
- Your research records will be labeled with a code number and your initials and will be kept in a safe area in in Dr. Verghese Cherian's office.

- A copy of this signed consent form will be included in your HMC medical record. This means that other HMC healthcare providers will know you are in this study.

In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

7b. How will my identifiable health information be used?

If you give your consent, health information that can be traced to you will be collected for this research study. In general, under federal law, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use, and share your health information for research and why they may need to do so. We will use and disclose your information only as described in this form and in the HMC Privacy Notice.

The research team may use the following health information:

- Past, present, and future medical records
- New health information from tests, procedures, visits, interviews, or forms filled out as part of this research study.

The following people/groups may see, use, and share your identifiable health information:

- HMC/PSU research staff involved in this study
- The HMC/PSU Institutional Review Board (IRB), a group of people who review the research study to protect subjects' rights and welfare
- The HMC/PSU Human Subjects Protection Office
- The HMC/PSU Research Quality Assurance Office
- Non-research staff within HMC/PSU who need this information to do their jobs (such as for treatment, payment (billing), or health care operations)
- Federal and state agencies (such as the U.S. Food and Drug Administration, the Office for Human Research Protections, the Department of Health and Human Services, the National Institutes of Health, and other U.S. or foreign government bodies that oversee or review research)
- The HMC/PSU pharmacy
- People or groups that we hire to do work for us, such as data storage companies, insurers, and lawyers
- Organizations that provide independent accreditation and oversight of hospitals and research

These groups may also review and/or copy your original PSU/HMC records while looking at the results of the research study. It is possible that some of the other people/groups who receive your health information may not be required by Federal privacy laws to protect your information. We share your information only when we must, and we ask anyone who receives it from us to protect your privacy.

Because research is an ongoing process, your permission for the use, storage and sharing of your health information will continue indefinitely.

Your privacy rights:

- You have the right to refuse to sign this form that allows us to use and share your health information for research; however, if you don't sign it, you will not be able to take part in this research study.
- You have the right to withdraw your permission for us to use or share your health information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing using the address on the front of this form. Once permission is withdrawn, you cannot continue to take part in the study.
- If you withdraw your permission, we will stop collecting health information about you for this study; we may continue to use and share your health information that we already have if it is necessary for safety and scientific soundness of the research study; and we will not be able to take back information that has already been used or shared with others.
- You have the right to see and get a copy of your health information that is used or shared for treatment or for payment. However, you may not be allowed to see or copy certain health information that is a part of this research study. This is only for the period of the study. You will be allowed to see that information when the entire research study is complete.

8. What are the costs of taking part in this research study?

8a. What will I have to pay for if I take part in this research study?

Costs of tests and procedures that are only being done for the research study:

- The sphenopalatine block with lidocaine will be provided by at no cost to while you take part in this study.
- You and/or your insurance company will not be charged for the cost of any tests or procedures that are required as part of the research and are outside the standard of care (what is normally done) for your condition.
- The research-related tests and procedures that will be provided at no cost to you include: the nerve block, and the use of research questionnaires.

For costs of medical services for care you would receive even if you were not in this research study:

- You and/or your insurance company will be responsible for the cost of routine medications, tests and procedures that you would receive even if you were not in this research.
- You and/or your insurance company will be billed for the costs of these routine tests and procedures in the usual manner.
- You will be responsible for any co-payments, co-insurance and deductibles that are standard for your insurance coverage.
- You will be responsible for any charges not reimbursed by your insurance company.
- Some insurance companies may not pay for routine costs for people taking part in research studies. Before deciding to be in this research you should check with your insurance company to find out what they will pay for.

If you have any questions about costs and insurance, ask the research study doctor or a member of the research team.

8b. What happens if I am injured as a result of taking part in this research study?

It is possible that you could develop complications or injuries as a result of being in this research study. If you experience a side effect or injury and emergency medical treatment is required, seek treatment immediately at any medical facility. If you experience a side effect or injury and you

believe that emergency treatment is not necessary, you should contact the principal investigator listed on the first page of this consent form as soon as possible and the principal investigator will arrange for medical treatment.
When you sign this form you are not giving up any legal right to seek compensation for injury.

HMC/PSU compensation for injury

- There are no plans for HMC/PSU to provide financial compensation or free medical treatment for research-related injury.
- If an injury occurs, medical treatment is available at the usual charge.
- Costs will be charged to your insurance carrier or to you.
- Some insurance companies may not cover costs associated with research injuries.
- If these costs are not covered by your insurance, they will be your responsibility.

9. Will I be paid to take part in this research study?
You will not receive any payment or compensation for being in this research study.

10. Who is paying for this research study?
Anesthesia Department research funds will be used to support this research study.

11. What are my rights if I take part in this research study?
Taking part in this research study is voluntary.

- You do not have to be in this research.
- If you choose to be in this research, you have the right to stop at any time.
- If you decide not to be in this research or if you decide to stop at a later date, there will be no penalty or loss of benefits to which you are entitled.

During the course of the research you will be provided with any new information that may affect your health, welfare or your decision to continue participating in this research.
If you stop being in the research, already collected data may not be removed from the study database. You will be asked whether the investigator can collect medical information from your routine medical care. If you agree, this data will be handled the same as research data. If you withdraw completely from the research study, no further information will be collected and your participation will end. You may discontinue taking part at any time without penalty or loss of benefits to which you are otherwise entitled.

Your research team may take you out of the research study without your permission.

- If the SP ganglion block cannot be performed due to any narrowing of nasal passages, or you cannot tolerate the procedure

12. If I have questions or concerns about this research study, whom should I call?
Please call the head of the research study (principal investigator), Dr. Verghese Cherian at 717-531-6926 or the Anesthesia doctor on 24-hour call at 717-531-8521 if you:

- Have questions, complaints or concerns about the research
- Believe you may have been harmed by being in the research study

You may also contact the research protection advocate in the HMC Human Subjects Protection Office (HSPO) at 717-531-5687 if you:

- Have questions regarding your rights as a person in a research study.
- Have concerns or general questions about the research.

- Have questions about your privacy and the use of your personal health information.
- You may also call this number if you cannot reach the research team or wish to offer input or to talk to someone else about any concerns related to the research.

You may visit the HSPO's web site at http://pennstatehershey.org/irb under research subject information for:

- Information about your rights when you are in a research study;
- Information about the Institutional Review Board (IRB), a group of people who review the research to protect your rights; and
- Links to the federal regulations and information about the protection of people who are in research studies. If you do not have access to the internet, copies of these federal regulations are available by calling the HSPO at (717) 531-5687.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

INFORMED CONSENT AND AUTHORIZATION TO TAKE PART IN RESEARCH

Signature of Person Obtaining Informed Consent

Your signature below means that you have explained the research to the subject or subject representative and have answered any questions he/she has about the research.

_____	_____	_____	_____
Signature of person who explained this research	Date	Time	Printed Name

(Only approved investigators for this research may explain the research and obtain informed consent.)

Signature of Person Giving Informed Consent and Authorization

Before making the decision about being in this research you should have:

- Discussed this research study with an investigator,
- Read the information in this form, and
- Had the opportunity to ask any questions you may have.

Your signature below means that you have received this information, have asked the questions you currently have about the research and those questions have been answered. You will receive a copy of the signed and dated form to keep for future reference.

Signature of Subject

By signing this consent form, you indicate that you voluntarily choose to be in this research and agree to allow your information to be used and shared as described above.

_____	_____	_____	_____
Signature of Subject	Date	Time	Printed Name