RUTGERS
Robert Wood Johnson
Medical School

CONSENT TO TAKE PART IN A RESEARCH STUDY

TITLE OF STUDY: A Comparison of the Efficacy of Sphenopalatine Ganglion Block (SPGB) with 5% Lidocaine versus Epidural Blood Patch (EBP) for the Treatment of Post-Dural Puncture Headache (PDPH)

Principal Investigator: William Grubb, MD, DDS

This consent form is part of an informed consent process for a research study and it will provide information that will help you/your child to decide whether you/your child wish to volunteer for this research study. It will help you/your child to understand what the study is about and what will happen in the course of the study.

If you/your child have questions at any time during the research study, you/your child should feel free to ask them and should expect to be given answers that you/your child completely understand.

After all of your/your child's questions have been answered, if you/your child still wish to take part in the study, you/your child will be asked to sign this informed consent form.

The study doctor, William Grubb, MD, DDS, or another member of the study team will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

You/your child are not giving up any of your legal rights by volunteering for this research study or by signing this consent form.

Sponsor of the Study: Department of Anesthesiology, Rutgers-Robert Wood Johnson Medical School.

Why is this study being done?

This study is being done because you/your child have a headache after a spinal procedure, which is called a post dural puncture headache (PDPH). A post dural puncture headache (PDPH) is caused from an injury to the covering of the spinal canal following epidural anesthesia, or following a diagnostic procedure such as a spinal tap or myelogram.

This study is designed to compare two different procedures for the treatment of PDPH: the epidural blood patch (or EBP) is the standard treatment for PDPH and will be compared to the

experimental treatment called the sphenopalatine ganglion block (or SPGB). SPGB is less invasive than the EBP.

The SPGB procedure is done by placing a cotton tip applicator with 5% Lidocaine gel into the middle portion of each side of the nose, followed by 1% Lidocaine solution that is injected into the applicator to reach the back of the nasal cavity. The ganglion is below the nasal tissues.

An epidural blood patch (EBP) is done by starting a sterile IV in the arm to obtain approximately one tablespoon of sterile blood. Then, using a sterile technique, an anesthesiologist places an epidural needle in the center of your back. The sterile blood is placed in the epidural space to seal the spinal fluid leak. This will relieve the post dural puncture headache.

Why have you/your child been asked to take part in this study?

You/your child are being asked to participate in this study because you/your child have been diagnosed with Post Dural Puncture Headache. You are age 13 or older and referred from a neurologist or other health care provider to the Pain Service at Rutgers-Robert Wood Johnson Medical School / Robert Wood Johnson University Hospital or you/your child are a patient in the Emergency Room of the Hospital.

Who may take part in this study? And who may not?

You may participate if:

1. Male and females ages 13-92
2. You/your child have formal diagnosis of Post Dural Puncture Headache

You may not participate if:

1. You are less than 13
2. You/your child will be excluded if they are already being treated with lidocaine (patch or other vehicle for chronic pain)
3. You/your child has untreated heart failure
4. You/your child are Pregnant
5. You/your child had a recent neurologic event such as a stroke or mini-stroke
6. You/your child are unwilling to comply with study procedures and follow-up

How long will the study take and how many subjects will participate?

We plan to enroll 210 subjects at Rutgers-Robert Wood Johnson Medical School. These subjects will be referred through the following departments; Pain Medicine, Pediatrics, Neurology and Emergency Medicine (ER) at RWJUH. You/your child's individual participation will continue for up to 4 weeks of active study visits to the Pain Clinic at Rutgers-Robert Wood Johnson

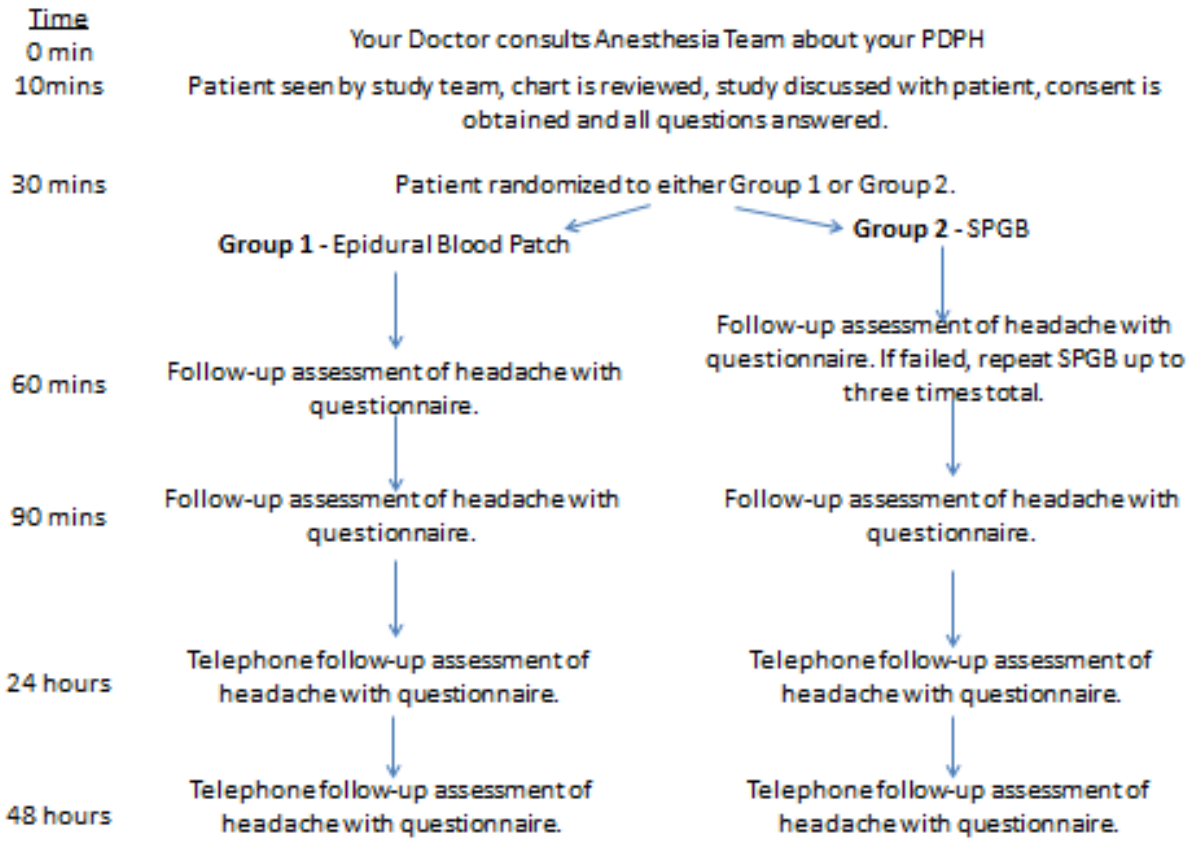
Medical School. You/your child will participate in a safety visit 2-4 weeks after the active treatment period.

What will you/your child be asked to do if you take part in this research study?

You/your child will be randomized to one of 2 treatment groups (assigned by a flip of a coin to one of 2 treatment groups). You/your child will be asked to complete headache questionnaires throughout the study.

If you/your child are randomized into the SPGB group, blood pressure, heart rate, pulse, and basic vital signs that are routinely done at doctor's office visits will be done. We will also look at pulse oximetry (measures the amount of oxygen in your/your child's blood) readings during the SPGB procedure. Pulse oximetry is a painless measurement that will be monitored during the procedure. This will be done using a clip that fits over the top and bottom of the first part of one of the finger. This may be done by non-study personnel such as the nurse taking care of the patient. You/your child will be asked to complete an additional questionnaire approximately 20 minutes after the procedure is completed. Lidocaine, which is the medication that we will be using for the SPGB, is a standard medication for pain.

If you/your child are randomized into the Blood Patch Group, you/your child will have approximately 1 tablespoon of blood drawn sterilely by the anesthesiologist from a vein in your arm and then this same blood will be immediately and with sterile technique be injected into your/your child's epidural space. This will create a type of "band aide" that patches the leak of the spinal fluid which is why you/your child are having symptoms of severe headache. The epidural blood patch will provide you/your child with relief from the Dural Puncture Headache.



What are the risks and/or discomforts you/your child might experience if you take part in this study?

Risks for SPG Block Procedure: (Complication rates are estimated based on recent literature review)

Local Discomfort (<5%)
Bitter taste in back of the throat (~50%)
Difficulty talking (<5%)
Oral numbness (<5%)
Difficulty eating and drinking (<1%)
Bloody drainage in the nose most notable on the application used to apply the lidocaine (<1%)

It is recommended that you/your child do not eat or drink for up to 2 hours after the SPGB Procedure.

Risks of Epidural Blood Patch are: (this can occur less than 1% of the time)

Infection
Hematoma (collection of blood in and around the back area)
Back pain
Recurring Dural Puncture Headache

Are there any benefits for you/your child if you choose to take part in this research study? The benefits of taking part in this study may be:

1. Potential for reducing the duration of the post dural puncture headache
2. Potential for reducing the amount of pain medications required to achieve relief from the post dural puncture headache.

There may be no benefits to you/your child from taking part in this study.

What are your/your child's alternatives if you don't want to take part in this study?

You/your child may use caffeine enriched products such as coffee and tea, other prescribed pain medications OR you/your child may require prolonged hydration / IV fluids that are administered usually in the hospital. (IV fluids are given into a vein to help reduce your Post Dural Puncture Headache).

How will you/your child know if new information is learned that may affect whether you/ your child are willing to stay in this research study?

During the course of the study, you will be updated about any new information that may affect whether you/your child are willing to continue taking part in the study. If new information is learned that may affect you/your child after the study or after your/your child's follow-up is completed, you will be contacted.

Will there be any cost to you/your child to take part in this study?

Your insurance company / third party payer will be billed for whichever procedure you/your child have done as both of these procedures are standard practice for severe headaches to relieve the pain and other symptoms you/your child might be experiencing.

Will you/your child be paid to take part in this study?

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

How will information about you/your child be kept private or confidential?

All efforts will be made to keep the personal information in your/your child's research record confidential, but total confidentiality cannot be guaranteed.

All measurements will be recorded on a case report form. All data will be kept in locked file cabinets in Dr. Grubb's office at the Clinical Academic Building Suite 3100, with limited access to study personnel. Your/your child's study files will be coded with your/your child's initials and a unique study number. All information will be kept confidential, the link to PHI (Personal Health Information) will be stored separate from the study files, and will be destroyed after the completion of the study.

A description of this clinical trial will be available on ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you/your child. At most, the Web site will include a summary of the results. You can search this website at any time.

What will happen if you/your child are injured during this study?

Subjects in this study will be exposed to certain risks of personal injury, which include: slight discomfort during the SPGB procedure and some blood drainage from nose that may be seen on the applicator. From the Epidural Blood Patch, slight risks of infection and back pain have been reported. In addition, it is possible that during the course of this study, new adverse effects of lidocaine and Epidural Blood Patch that result in personal injury may be discovered. The University will make appropriate referrals for medical and/or dental treatment for subjects who sustain personal injuries or illnesses as a direct consequence of participation in the research. The subject's health insurance carrier or other third-party payer will be billed for the cost of this treatment; provided that the University shall not submit to federally funded programs, e.g., Medicare, Medicaid or CHAMPUS, for reimbursement first if submission to such programs is prohibited by law. No financial compensation will be provided by the University and no other type of assistance is available from the University.

What will happen if you/your child do not wish to take part in the study or if you/your child later decide not to stay in the study?

Participation in this study is voluntary. You/your child may choose not to participate or you may change your mind at any time. You/your child will still be treated for your post dural puncture headache by the doctor you have an appointment with regardless of your decision to participate in this clinical study. This is considered standard of care treatment. Your/your child's standard of care treatment may be the same medications we are studying (if the doctor feels that this is the best way to treat you/your child) but we will not include any of your/your child's treatment or results in this study.

You may also withdraw your/your child's consent for the use of data already collected about you or your child, but you must do this in writing to:

Dr. William Grubb, MD, DDS
Rutgers-Robert Wood Johnson Medical School
Clinical Academic Building Suite 3100,

New Brunswick, NJ 08901

If you/your child decide to withdraw from the study for any reason, you/your child may be asked to return for at least one additional visit for safety reasons. Additionally, the information that was already collected for research purposes will NOT continue to be used.

Who can you call if you/your child have any questions?

If you/your child have any questions about taking part in this study or if you feel you/your child may have suffered a research related injury, you can call the study doctor:

William Grubb, MD, DDS
Dept. of Anesthesiology, Rutgers-Robert Wood Johnson Medical School
732-235-7827

If you have any questions about your/your child's rights as a research subject, you can call:

IRB Director
(732)-235-9806 New Brunswick/Piscataway

What are your/your child's rights if you decide to take part in this research study?

You/your child have the right to ask questions about any part of the study at any time. You should not sign this form unless you have had a chance to ask questions and have been given answers to all of your questions.

AUTHORIZATION TO USE YOUR/YOUR CHILD'S HEALTH INFORMATION FOR RESEARCH PURPOSES

Because information about you/your child and your health is personal and private, it generally cannot be used in this research study without your written authorization (permission). If you sign this consent form, it will provide that authorization. The next few paragraphs tell you about how your/your child's health information will be used or disclosed in the study. Your/your child's information will only be used in accordance with this authorization and informed consent form as required or allowed by law. Because we are committed to protecting your/your child's health information, some of the paragraphs that follow repeat what we described to you earlier in this consent form about what information we will collect about you/your child, how we will use it, when or if it will be shared with others, and the measures we will take to protect your/your child's privacy and the confidentiality of your/your child's personal information.

Please read this authorization section and the consent form carefully. Ask questions if anything is not understandable to you.

What is the purpose of this research study and how will my/my child's health information be utilized in the study?

The purpose of this study is to determine if SPGB is superior to an Epidural Blood Patch in the treatment of post dural puncture headaches in subjects diagnosed with PDPH. We will be using the headache questionnaires that you complete to analyze the study question. We do plan to publish or share our results to others in a peer-reviewed journal or at national and international conferences. These are places where specialists discuss the care and treatment of your/your child's condition in order to help improve the care you receive. These are generally professional meetings that doctors and medical professionals attend to improve the care in their daily practices.

Do I have to sign this authorization form?

You do not have to sign this authorization form. But if you do not, you/your child will not be able to participate in this research study and receive any research-related products. However, signing the form is not a condition for receiving any medical care outside the study.

If I sign, can I revoke my authorization or withdraw my information later?

If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your/your child's health information (and to discontinue any other participation in the study) at any time. After any revocation, your/your child's health information will no longer be used or disclosed in the study, except to the extent that the law allows the researchers to continue using and disclosing your or your child's information. Therefore, you should be aware that the researchers may continue to use and disclose the health information that was provided before you withdrew your authorization if necessary to maintain integrity of the research or if the data had already been stripped of all identifiers.

If you wish to revoke your authorization for the research use or disclosure of your/your child's health information in this study, you may do so in writing by contacting:

William Grubb, MD, DDS
Rutgers-Robert Wood Johnson Medical School
Clinical Academic Building Suite 3100,
New Brunswick, NJ 08901
732-235-7827

What personal information will be used or disclosed?

After we have treated the headache, we will ask you/your child a series of questions about you/your child's symptoms at specific time points. The information we gather during these encounters is the only information that will be disclosedin this study. No other personal or health information will be disclosed in this study. We will be checking your patient chart in order to confirm that you meet our inclusion and exclusion criteria. Our inclusion criteria includes your age. Our exclusion criteria includes your age, language, pregnancy status, allergies, history of heart disease, current medications, past surgical history, platelet count, indicators of sepsis, skin infections in lumbar spine, sinusitis, nasal polyps, nasal surgery, neurological events, current anticoagulant therapy or prior treatment history with SPGB or EBP, The results of this study will help provide doctors with clarity on the best treatment methods for PDPH.

Who may use or disclose the information?

The following parties are authorized to use and/or disclose your/your child's health information in connection with this research study:

- The Rutgers University-Institutional Review Board
- The Research Team in the Department of Anesthesiology
- Rutgers-Robert Wood Johnson University Hospital
- FDA
- The Office for Human Research Protections in the U.S. Department of Health and Human Services

Who may receive/use the information?

The parties listed in the preceding paragraph may disclose your/your child's health information to the following persons and organizations for their use in connection with this research study:

- The Rutgers University-Institutional Review Board
- The Research Team in the Department of Anesthesiology
- Rutgers-Robert Wood Johnson University Hospital
- FDA
- The Office for Human Research Protections in the U.S. Department of Health and Human Services.

All clinical trials may be monitored by the FDA (Food and Drug Administration) without notice.

When will my authorization expire?

Your authorization for the use and /or disclosure of your/your child's health information will expire: "There is not a set date at which your authorization will expire. This is because the

information used and created during the study may be analyzed for many years, and it is not possible to know when this will be complete."

Will access to my research study record be limited during the study?

To maintain the integrity of this research study, you may not have access to any health information developed as part of this study until it is completed. At that point, you would have access to such health information if it were used to make medical or billing decisions about you or your child and was included in your official medical record.

See consent form below

AGREEMENT TO PARTICIPATE (Adult)

I have read this entire form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form or this study have been answered.

Subject Name:_____

Subject Signature:_____ Date:_____

Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed the full contents of the study including all of the information contained in this consent form. All questions of the research subject and those of his/her parent or legal guardian have been accurately answered.

Investigator/Person Obtaining Consent:_____

Signature:_____ Date: _____

AGREEMENT TO PARTICIPATE (Parent of Child age 13-17)

I have read this entire form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form or this study have been answered.

I am the [ ] parent or [ ] legal guardian of _____ (name of child) and I agree for my child to take part in this research study.

Subject/Child's Name:_____

Parent's Signature:_____ Date:_____

Signature of Investigator/Individual Obtaining Consent:

To the best of my ability, I have explained and discussed the full contents of the study including all of the information contained in this consent form. All questions of the research subject and those of his/her parent or legal guardian have been accurately answered.

Investigator/Person Obtaining Consent:_____

Signature:_____ Date: _____