

Main Study Informed Consent Form and HIPAA Authorization

Study Title: Occipital Nerve Blocks for Acute Treatment of Pediatric Migraine

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Principal Investigator: Dr. Christina Szperka (215) 590-1719

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Ask to page the Neurology
Fellow on call

You and your child may be eligible to take part in a research study. This form gives you important information about the study. It describes the purpose of this research study, and the risks and possible benefits of participating.

If there is anything in this form you do not understand, please ask questions. Please take your time. You do not have to take part in this study if you do not want to. If you take part, you can leave the study at any time.

In the sections that follow, the word “we” means the study doctor and other research staff. If you are a parent or legal guardian who is giving permission for a child, please note that the word “you” refers to your child.

Parents or guardians may also be eligible to participate in this study and its research questionnaire/survey portion. Please note that this study does not require parents/guardians to undergo any other research procedure.

Why are you being asked to take part in this study?

You are being asked to take part in this research study because you have a bad headache that has not gone away with usual medicines, and additional treatment might help.

What is the purpose of this research study?

The purpose of this research study is to see if occipital nerve blocks can treat children with bad headaches. Occipital nerve blocks will put medicine over the nerves in the back of your head.

How many people will take part?

Up to 97 primary child subjects will be enrolled and 97 parents/legal guardians will also be enrolled. 194 subjects will be enrolled in total.

What is involved in the study?

During the study, we will ask you to describe your headache. We will also ask you, and your parent or guardian, how you feel about the treatments. In this study, once you have signed consent, to make sure you are eligible, we will first start with some additional screening procedures (if not already done): pregnancy test, interview, and/or medical

chart review. Then, we will apply numbing cream on the back of your head. This step may make the headache go away and may decrease the pain of injection. After 30 minutes, if your headache is gone, or so low that you do not want any more treatment, we will not do any more research treatments. If you still have a headache, we will inject the nerves on the back of your head with either lidocaine or saline. The choice of medicine will be decided at random, like the toss of a coin. There is an equal chance that you will receive either study medicine.

If the research treatments do not make your headache go away, the study doctor will discuss non-study treatments that can be tried. If you decide not to participate in the study, we will discuss with you the same non-study treatments.

How long will you be in this study?

If you agree to take part, your participation will last about 1 month. You will have to complete 1 in-person study visit and then, when you go home, you will be asked to answer questions, daily, in a headache diary and other surveys for 28 days.

What are the study procedures?

Some of the procedures in this study will be repeated several times. The study involves the following tests and procedures.

Interviews: A team member will take your medical history, along with a listing of any medications you are taking. Throughout the study, you will be asked to report if you think that anything bad has happened as a result of the study.

Medical Record Review: We will review your medical records throughout the study to collect information about your medical history, current health, headache diagnosis, treatments, and medications.

Physical Examination: Exams will be conducted during the study including complete medical and neurological examinations as well as measurements of height, weight, blood pressure, heart rate, and head circumference. These exams will also include a fundoscopic exam in which we will look at your eyes using different instruments. The light from the instruments used may seem very bright.

Nerve Block Procedure: You will have numbing cream applied to the back of your head. In a clinic room, the study doctor will have you sit on a chair in front of the exam table and lay your forehead on the table. She will apply the cream onto your scalp under your hair on the back of your head. You can then sit up and move around while the cream takes effect. After 30 minutes, the cream will be wiped off with gauze.

If you still have a headache after 30 minutes, the study doctor will perform occipital nerve blocks. She will have you sit in a chair and put your forehead on the exam table again. She will feel for the bones in the back of your head, and push to find a sore spot, which corresponds to the occipital nerve. She will then inject lidocaine or saline with a small needle over the nerve. She will repeat this on the other side of your head. Each injection will take a few seconds. During that time, you need to hold still, but then you can move around again.

Pregnancy Test (Female subjects only): We will collect urine to complete a pregnancy test. If you are female and have already started having periods, you will be asked

to take a urine pregnancy test before starting the study. The results will be shared with you and not with your parent(s). If you are found to be pregnant, you will not be able to participate/continue participating in the study. We encourage you to share the results of a positive pregnancy test with your parents but we cannot make you.

Questionnaires: You will be asked to complete a few questionnaires throughout the study. We will ask you how the pain affects your life and your opinion about the study treatment(s). We will also ask your parent or guardian to complete some of these questionnaires. These short questionnaires will take about 5 minutes to complete.

Headache Diary: You will be asked to keep a daily diary of headache symptoms for 28 days following the Study Visit. Each day, answering the questions will take about 5 - 7 minutes to complete.

You can choose to answer the questions on paper or electronically through text messages. If you prefer to keep a paper diary, then, weekly, we will ask you to fax or scan and email the pages. If you prefer to use texting, then our CareBot will text you questions every day. Some of these text messages will include links. You will be asked to click on the link and answer more questions.

If you forget to respond, our CareBot will remind you. If you do not respond to CareBot or you do not send us any completed questions on paper, then our study team will call you.

What are the risks of this study?

Taking part in a research study involves inconveniences and risks. If you have any questions about any of the possible risks listed below, you should talk to your study doctor or your regular doctor.

While in this study, you are at risk for side effects. Based on both the experience at CHOP and studies from other places, minor side effects are common but major side effects are very rare.

Risks associated with lidocaine cream:

- Numbness or abnormal sensation at the site of the cream is common
- Redness or irritation at the site of the cream can occur
- Rash is uncommon

Risks associated with a nerve block procedure:

- Mild nervousness is common. Some people also feel silly or giddy after the procedure ends.
- Panic feelings including nervousness, breathing fast, racing heart, and hot flashes occur slightly more often, but go away after the procedure stops or ends.
- Syncope (passing out) related to anxiety happens in less than 1 per 100 people



Risks associated with lidocaine or saline injection for nerve block:

- Pain or burning with injection
- Numbness of the skin
- Dizziness
- Worsened headache

Reproductive Risks:

There are no known reproductive risks involved in this study. The lidocaine and saline used in the nerve block injections are not known to cause any complications in pregnancy for either the pregnant woman or fetus. Neither substance is expected to cause problems for breast-fed infants.

Risks of Breach of Privacy and Confidentiality:

As with any study involving collection of data, there is the possibility of breach of confidentiality of data. Every precaution will be taken to secure participants' personal information to ensure confidentiality.

At the time of participation, each participant will be assigned a study identification number. This number will be used on data collection forms and in the database instead of names and other private information. A separate list will be maintained that will link each participant's name to the study identification number for future reference and communication.

Risks associated with completing questionnaires and interviews:

There are no physical risks but you might experience momentary embarrassment or discomfort. You do not have to answer any questions that make you too uncomfortable.

Risks associated with physical exams:

There are no physical risks but you might experience momentary embarrassment or discomfort. The exam is similar to those that are performed as part of routine medical care. There is very little risk of harm from the eye examination.

When blood pressure is taken during physical exams, the blood pressure cuff may cause discomfort or bruising to the upper arm.



Are there any benefits to taking part in this study?

Your headache might get better with the study procedures. Data from previous studies show that nerve blocks usually help headache, regardless of what medicine is used. However, we cannot guarantee or promise that you will receive any direct benefit by participating in this study. The knowledge gained from this research may help doctors determine if occipital nerve blocks with either numbing medicine or saline are helpful as an acute headache treatment in children.

Do you need to give your consent in order to participate?

If you decide to participate in this study, you must sign this form. A copy will be given to you to keep as a record.

What are your responsibilities?

Please consider the study time commitments and responsibilities as a research subject when making your decision about participating in this study. You will need to remain still for a few seconds during the injections and follow the study doctor's instructions.

What happens if you decide not to take part in this study?

Participation in this study is voluntary. You do not have to take part in order to receive care at CHOP. If you decide not to take part or if you change your mind later there will be no penalties or loss of any benefits to which you are otherwise entitled.

Can you stop your participation in the study early?

You can stop being in the study at any time. You do not have to give a reason.

Can the study doctor take you out of the study early?

- You cannot meet all of the requirements of the study.
- You have a bad reaction to the cream or the first nerve block injection. If this happens we will not do any more study treatments, but we will ask you to keep a diary of symptoms for 28 days after the Study Visit.

What choices do you have other than this study?

There are options for you other than this study including:

- Receiving usual care for your headache outside this study
- Not participation in this study.
- You may discuss other options available to you with your doctor.

What about privacy, authorization for use of Personal Health Information (PHI) and confidentiality?

As part of this research, health information about you will be collected. This will include information from medical records, procedures, interviews, tests and questionnaires that you and your parent or guardian complete. Information related to your medical care at CHOP will go in your medical record. This could include physical exams or tests done in the clinical lab. Medical records are available to CHOP staff. Staff will view your records



only when required as part of their job. Staff are required to keep your information private. Information that could identify you will not be shared with anyone - unless you provide your written consent, or it is required or allowed by law. Laboratory test results will appear in your medical record. We will do our best to keep your personal information private and confidential. However, we cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law.

The results of this study may be shown at meetings and published in journals to inform other doctors and health professionals. We will keep your identity private in any publication or presentation.

Several people and organizations may review or receive your identifiable information. They will need this information to conduct the research, to assure the quality of the data, or to analyze the data. These groups include:

- Members of the research team and other authorized staff at Children’s Hospital of Philadelphia (CHOP).
- People from agencies and organizations that perform independent accreditation and/or oversight of research; such as the Department of Health and Human Services, Office for Human Research Protections.
- An Independent Medical Monitor performing data and safety monitoring for this study
- The National Institutes of Health who is sponsoring this research
- Researchers at outside hospitals including University of Pennsylvania and Cincinnati Children’s Hospital who will help with the analysis of study data. The data will be labeled with a unique code and these researchers will not know who you are. Private information such as name, birth date or medical record number will not be shared.
- Patiently, Inc. and its representatives, who will help with setting up our texting CareBot for this study.

By law, CHOP is required to protect your health information. The research staff will only allow access to your health information to the groups listed above. By signing this document, you are authorizing CHOP to use and/or release your health information for this research. Some of the organizations listed above may not be required to protect your information under Federal privacy laws. If permitted by law, they may be allowed to share it with others without your permission.

There is no set time for destroying the information that will be collected for this study.

Your permission to use and share the information and data from this study will continue until the research study ends and will not expire. Researchers continue to analyze data for many years and it is not possible to know when they will be completely done.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The



researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of Federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

The Certificate of Confidentiality does not prevent the researchers from disclosing, without your consent, information that they are required by law to disclose to government authorities. For example, researchers must comply with laws requiring the reporting of suspected child abuse and neglect and communicable diseases.

Can you change your mind about the use of personal information?

You may change your mind and withdraw your permission to use and disclose your health information at any time. To take back your permission, it is preferred that you inform the investigator in writing.

Dr. Christina Szperka
The Children's Hospital of Philadelphia
Division of Neurology
34th Street and Civic Center Blvd.
Philadelphia, PA 19104

In the letter, state that you changed your mind and do not want any more of your health information collected. The personal information that has been collected already will be used if necessary for the research. No new information will be collected. If you withdraw your permission to use your personal health information, you will be withdrawn from the study.

Additional Information

An Independent Medical Monitor will be reviewing the data from this research through the study.

You will be informed if changes to the study are needed to protect your health. You will be told about any new information that could affect your willingness to stay in the study, such as new risks, benefits or alternative treatments.



Financial Information

While you are in this study, the cost of your usual medical care – procedures, medications and doctor visits – will continue to be billed to you or your insurance. If your headache does not get better with study treatments, or gets worse with study treatments, you will be offered other usual care options. Those non-study treatments will be billed to you or your insurance.

Will there be any additional costs?

There may be additional costs to you by taking part in this study; standard message and data rates or charges may apply when receiving or sending text messages or completing the web-based questionnaires on a mobile device. Check with your wireless carrier if you have any questions or concerns about your plan or possible costs. You will not be reimbursed for any of these associated or additional costs.

The NIH is providing financial support and material for this study. The following research procedures, study drugs and study visits will be paid by the NIH:

- Cost of parking
- Cost of study drug
- Study doctor's time to perform procedures
- Urine pregnancy tests for pregnancy, if applicable

Will you be paid for taking part in this study?

Parents will be reimbursed a per diem of \$20 to offset the cost of travel and parking.

Participants will be paid \$25 for their time and effort for the study visit, and an additional \$25 if at least 23 days (out of 28) worth of the headache diary and survey questions are completed.

If you receive payment using a bankcard, the bank will have access to identifiable information. The bank will not have access to any medical information.

We may share your data with third parties (other researchers/institutions or for profit companies). If there are patents or products that result from the research, the third parties may make money from the research. You will not receive any financial benefit from research done on your data.

Who is funding this research study?

The National Institutes of Health is providing funding for this study.

What if you have questions about the study?

If you have questions about the study, call the study doctor, Dr. Szperka at 215-590-1719. You may also talk to your own doctor if you have questions or concerns.

The Institutional Review Board (IRB) at The Children's Hospital of Philadelphia has reviewed and approved this study. The IRB looks at research studies like these and makes sure research subjects' rights and welfare are protected. If you have questions about your rights or if you have a complaint, you can call the IRB Office at 215-590-2830.



A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. 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.

What happens if you are injured during the study?

If you are hurt or get sick from something that was done as part of this study, doctors at the clinic or hospital can arrange for emergency medical care. The Hospital does not offer financial compensation or payment for injuries due to participation in this research.

You and your insurance company will be billed for the costs of any care or injuries.

If you think you have been injured from taking part in this study, call Dr. Szperka at 215-590-1719. She can go over things with you, let you know of resources that may be available and give you information on what you need to do.

In case of injury resulting from this study, you will not lose any legal rights by signing this form.

Consent for Use of Data for Future Research

As part of the study, we will collect data. We may wish to use this information in a future study about headache or other conditions. Your information will be given a unique code and will not include information that can identify you. Any identifiable data will be stored on a secure electronic server at CHOP. A master list linking the code to information that can identify you may be kept permanently in a computer database at CHOP. Only the study doctors and those working with them on this study will be able to see information that can identify you.

If you leave the study, you can ask to have the data collected about you removed. You can also ask us to remove information that identifies you from the data.

Please indicate whether you will allow the data to be used for future research by putting your initials next to one of the following choices:

_____ (initials) The data may be used for this study only.

_____ (initials) The data may be used for other future research studies. If the data are shared outside of CHOP, no identifiable information will be included.

(Note: For Spanish speaking subjects, initialing will be performed by the study team member obtaining consent.)



Consent to Take Part in this Research Study and Authorization to Use and Disclose Health Information for the Research

The research study and consent form have been explained to you by:

Person Obtaining Consent

Signature of Person Obtaining Consent

Date

By signing this form, you are indicating that you have had your questions answered, you agree to take part and to allow your child to take part in this research study, and you are legally authorized to consent to your and your child's participation. You are also agreeing to let CHOP use and share the health information that will be collected for this study, as explained above. If you don't agree to the collection, use, and sharing of health information, you and your child cannot participate in this study.

NOTE: *A foster parent is not legally authorized to consent for a foster child's participation.*

Consent for Child's Participation

Name of Subject

Signature of Subject
(18 years or older)

Date

Name of Authorized Representative

Relation to subject:

Parent Legal Guardian

Signature of Authorized Representative

Date

Consent for Parent's Participation

Name of Parent or Guardian

Signature of Parent or Guardian

Date



Child Assent to Take Part in this Research Study

For children capable of providing assent:

I have explained this study and the procedures involved to _____ in terms he/she could understand and that he/she freely assented to take part in this study.

Person Obtaining Assent

Signature of Person Obtaining Assent

Date

This study has been explained to me and I agree to take part.

Signature of Subject (optional)

Date



STUDY SUMMARY DOCUMENT (NON-ENGLISH SPEAKERS)

Consent to Take Part in this Research Study and Authorization to Disclose Health Information for Research

Name of Child Subject

Name of Parent or Guardian Subject

Name of Authorized Representative
(if different than child subject)

Relation to subject:
 Parent Legal Guardian

The research study and consent form have been explained to the subject and parent/guardian.

By signing this form, you are indicating that you have answered the subject's or parent's/legal guardian's questions, they have agreed to take part in this research study and they are legally authorized to consent to their and their child's participation. They have also agreed to let CHOP use and share their and their child's health information as explained above. If they don't agree to the collection, use and sharing of their and their child's health information, they cannot participate in this study.

Person Obtaining Consent

Signature of Person Obtaining Consent

Date:

Witness/Interpreter

By signing this form, you are indicating that

- The information in the Summary Document as well as any additional information conveyed by the person obtaining consent was presented to the subject in a language preferred by and understandable to the subject; and
- The subject's questions were interpreted and the responses of the person obtaining consent were presented in a language preferred by and understandable to the subject.
- At the conclusion of the consent conference, the subject was asked in a language preferred by and understandable to the subject if s/he understood the information in the Summary Document as well as any additional information conveyed by the person obtaining consent (including responses to the subject's questions) and responded affirmatively.

Name of Witness/Interpreter

Signature of Witness/Interpreter

Date:



Child Assent to Take Part in this Research Study

For children capable of providing assent:

I have explained this study and the procedures involved to _____ in terms he/she could understand and that he/she freely assented to take part in this study.

Person Obtaining Assent

Signature of Person Obtaining Assent

Date

Witness/Interpreter

By signing this form, you are indicating that

- The information in the Summary Document as well as any additional information conveyed by the person obtaining assent was presented to the subject in a language preferred by and understandable to the subject; and
- The subject's questions were interpreted and the responses of the person obtaining assent were presented in a language preferred by and understandable to the subject.

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Name of Witness/Interpreter

Signature of Witness/Interpreter

Date

