Children's Healthcare of Atlanta
Consent to be in a Research Study

Title: Gabapentin Premedication to Reduce Postoperative Pain For Pediatric Tonsillectomy/Adenoidectomy: Randomized Control Trial

Principal Investigator: Margaret Gettis DNP, CPNP-PC

Sponsor's Name: Dudley Moore

If this form is being read by the parent or legal guardian, the term "you" refers to "your child."

General:

- You are being asked to be in a research study. This form explains what would happen if you join this research study.
- Taking part in this study is voluntary and it is entirely your choice.
- If you take part in this study, you may stop being in the study at any time.
- Your decision to join or not join the study will not affect your current or future medical care at Children's.
- It is important that you read and understand this form in order to decide whether or not you want to be a part of this study. Take as much time as you need.
- It is also important that you ask any questions that you may have and that you understand all the information in this form.

Why is this study being done?
The purpose of this study is to find out if one dose of the drug gabapentin given before surgery helps with pain after surgery compared to an inactive medicine (placebo) that does not have the drug, in kids having tonsils and adenoids out. Gabapentin is approved by the Federal Drug Administration (FDA) but not for how it is being used in this study. Gabapentin has been used for pain management after other surgeries. Your child is being asked to be a part because he or she is having tonsils and adenoids taken out with Dr. James Thomsen at Children's Healthcare of Atlanta, Scottish Rite. The number of kids in this study will be 50.

What will happen to you in the study?
Your child will get either one dose of gabapentin or placebo by mouth in liquid form before having Tonsil or Adenoids out. The choice of who gets the drug or who gets the inactive medicine (placebo) is done by random. Random is like flipping a coin to see which one they will get, the gabapentin or the placebo that does not contain any drug. You need to know your child will get all the usual pain drugs during and after having tonsils and adenoids out. The gabapentin or inactive medicine (placebo) will only be given one time before surgery. Taking part in the study is your choice. You do not have to take part if you or your child does not want to.

How long will you be in this study?
Your child will receive the drug or placebo by mouth right before having tonsils and adenoids out. The study will go for three days. After you go home, you will receive an email for three days to a secure web link to fill out your pain diary. You and your child may get phone calls from a Research Study Team Member to remind you to fill out the pain diary three times online. Your child will be asked to tell about their pain, any side effects, and pain drugs used. The study is done once you and your child fill out the pain diary three times online.

What are the possible risks to being in this study?
Gabapentin is a drug with few side effects. Less than 20% of the time the side effects could be sleepiness, dizziness, tiredness. Less than 1% of the times the side effect is seizures. People with

CHOA IRB#: 18-052
Children's IRB Approval Date: 7/3/2018
Children's IRB Expiration Date: 5/23/2019

kidney problems should not take Gabapentin. Your child will be closely checked because Anesthesia can cause the same side effects.

What are the possible benefits of being in this study?
Your child could take a drug that helps with pain after having tonsils and adenoids out or your child could take a placebo that will not help with pain after having tonsils and adenoids out. The drug may also help pain for kids having tonsils and adenoids out later.

What are the alternatives to being in this study?
The other choice is to not take part in the study. Your child will get all routine pain drugs during and after having tonsils and adenoids out even your child does not do the study.

What is the cost of being in this study?
- There is no cost to being in the study. The cost of the medication will be paid out of study funding; at no expense to you or your child and will not be billed to your insurance.
- You will be compensated using "ClinCard", which works like a debit card and is provided by Greenphire. When three phone interviews are completed, funds will be loaded onto your card. You will be able to use the funds in approximately 1 business day. The total that you can receive is $25.00. To issue your card, we need to give Greenphire some of your personal information (or your child's). If you do not wish to provide this information, you can still take part in the study, but you will not be paid. Banks and other financial institutions can access this information if they need to verify your identity when you use your card. Children's is required by law to report any payments we make to the IRS. To do this, the Finance department needs to keep you social security number on file. We are asking you to allow us to give your name, address, date of birth, research study name and social security number to Greenphire. If you want to receive email or text alerts when payments are made to you, we will ask you to provide your email or phone number as well. All of this information will be stored on computers owned by Greenphire. Greenphire will not have access to any other information collected during this study. Full instructions about using your card are included when we issue it. Please ask if you have any questions or concerns about the card or use of your personal information.

What if you are injured while in this study?
We will arrange for emergency care or medical treatment if you are injured by this research. Provision of such medical care does not imply any negligence or other wrongdoing on the part of Children's or any of the physicians or other personnel involved in individual care or services rendered. No further money has been set aside by Children's Healthcare of Atlanta, Inc. (or the Sponsor) other than what your insurance carrier may provide. You or your insurance company would be billed for the treatment. The only exception to this policy is if it is proved that your injury or illness is directly caused by the negligence of a Children's (or Sponsor) employee.

For more information about risks or if you believe you have been injured by this research, you should contact call the Principal Investigator, Dr. Margaret Gettis DNP, CPNP-PC at 404-785-8622.

What if there is new information about this study?
We will tell you about new things during the study that you may need to know or things that might make you want to stop participating in the study.

What if you have any questions or problems while in this study?
If you have any questions, concerns or complaints about this study call Principal Investigator, Dr. Margaret Gettis DNP, CPNP-PC at 404-785-8622. If you have any questions, concerns or complaints about your rights as a participant in this study, or would like to obtain information, or offer input, you can call the Children's Healthcare of Atlanta Institutional Review Board (IRB) at (404) 785-7477 or via email at irb@choa.org. The IRB is a group of people that approves all research in this hospital and follows all the rules and regulations made by government agencies about how research is done.

Who will be able to see your records of study participation?

Your records of participation in this study are not accessible to the general public and every effort will be made to maintain confidentiality. However, all records may be subject to subpoena by a court of law. Information that may be gained from this study will be used only for research and educational purposes. Information may be published in medical journals with permission of the Principal Investigator, but your identity will not be revealed or written in a way that you can be recognized. Additionally, identifying information will be available to people from the Children's Healthcare of Atlanta Human Research Protections Program (i.e., IRB, the Research Compliance Office, Office of Sponsored Programs, Office of Grants Administration, Grants Accounting, etc.), the Office for Human Research Protections, the Sponsor(s), and the Food and Drug Administration (FDA), Contract Research Organization (CRO)

A copy of this consent form will be placed in your medical record. Medical information collected during this study will become part of your hospital record, if the information is determined to be pertinent to your care. Medical records are considered permanent records; therefore, materials cannot be deleted from the record. Medical records are available to healthcare professionals at Children's and may be reviewed by Children's staff in their course of carrying out their responsibilities. Children's staff is required to maintain confidentiality in accordance with applicable laws and Children's policies. Information contained in your medical record may not be given to anyone unaffiliated with Children's in a way that could identify you without written consent, expect as required or permitted by law.

A description of this clinical trial will be available on 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.

Can I leave the study?

Taking part in this study is completely voluntary. You may decide not to take part in this study. If you take part in this study, you may stop being in the study at any time. Your decision to join or not to join the study will not affect your current or future medical care at Children's.

The study doctors may stop you from taking part in this study for any of the following reasons: you need treatment or medication that may not be taken while on the study or the PI feels it is in your best interest to be taken off this study; you do not follow study procedures or are not able to attend required study visits; withdraw of parent/guardian permission or the study sponsor decides to end the study.

Contacting Research Subjects for Future Studies

Do you give your permission to be contacted in the future by _____ (*insert investigator or staff*) regarding your willingness to participate in future research studies about how to prevent, detect, or treat _____ (*insert name of disease)*?

☐ Yes ☐ No _____Initials

Authorization to Release Protected Health Information for Research Purposes

Your health information is protected by a law called the Health Insurance Portability and Accountability Act (HIPAA) is a federal law passed to protect the privacy of your Protected Health Information (PHI). PHI is any information about you that could tell someone who you are. The following information will explain how we will use and disclose your PHI for this study.

What PHI will be collected for this study:

The PHI that we will use or share for the research study includes:

- Medical information about you including your medical history and medications.
- Laboratory test results, results of exams, procedures, interviews and tests you have before and during the study.

CHOA IRB#: 18-052
Children's IRB Approval Date: 7/3/2018
Children's IRB Expiration Date: 5/23/2019
APPROVED

Who will collect the information:

The research staff conducting the study will collect and copy your PHI. Your PHI will be used and shared for the conduct and oversight of this study, study related treatment and payment for such treatment. Your PHI will also be used to conduct normal business operations.

Who else will see the information:

- Research staff involved in this study;
- Other staff directly involved in your care that is related to the research or arises from it;
- Other researchers and centers that are part of this study, including people who oversee research at those institutions;
- People at Children's who oversee, advise and evaluate research and care or are involved in the study administration and billing. This includes offices within the Human Research Protections Program (i.e., Institutional Review Board, Research Compliance Office);
- People from agencies and organizations that provide accreditation and oversight of research;
- People that oversee the study information such as data safety and monitoring boards, clinical research organizations, data coordinating centers and others;
- Sponsors or others who fund the research;
- Government agencies that regulate research including the Food and Drug Administration, The Department of Health and Human Services, the National Institutes of Health, and public health and safety authorities;
- People or groups hired to provide services related to this research (i.e., service providers, laboratories, etc.);
- Your health insurer for portions of the research and related care that are considered billable

The Privacy Rule applies to doctors, hospitals, and other healthcare providers. Some of the groups listed above are not required to follow the Privacy Rule and may share your information with others, if other laws allow. However, other privacy protections may still apply. If you have a question about this, you may contact the Children's Privacy Office at 404-785-1516 and they can help you understand privacy and confidentiality.

How long does the permission last:

Because research is ongoing, this permission will not expire. However, you may cancel this permission at any time.

If you change your mind and want to cancel your permission, you must contact the study team; Dr. Margaret Gettis DNP, CPNP-PC, Principal Investigator, 1649 Tullie Circle, Atlanta, GA.30329 404-785-8622. At that point, researchers would not collect any more PHI, but may use or disclose information already collected for safety reasons, to verify research data or if required by law. If you cancel your permission, you will not be able to stay in the study.

Contact Information

You may use the following contact information to reach the appropriate person/office to address any questions or concerns you may have about this study:

For questions about the study, research-related injuries, emergencies or concerns, contact (Principal Investigator, Dr. Margaret Gettis DNP, CPNP-PC, 1649 Tullie Circle, Atlanta, GA 30329. 404-785-8622).

For questions about your rights as a research participant or if you have questions, concerns or complaints about the research, contact the IRB at 404-785-7477 or irb@choa.org.

Informed Consent and Authorization:

Your signature below indicates that:

CHOA IRB#: 18-052
Children's IRB Approval Date: 7/3/2018
Children's IRB Expiration Date: 5/23/2019

- You have read this informed consent form and have been given enough time to consider the decision to participate in the study;
- The research study has been satisfactorily explained to you;
- You have been given the chance to ask questions and have had those questions answered to your satisfaction;
- You understand this study is voluntary and you can withdraw at any time;
- You are signing this consent form prior to participation in any research activities; AND
- You agree to participate in this research study and allow the use of associated protected health information (PHI) as described above.

You will receive a copy of this form.

CHOA IRB#: 18-052
Children's IRB Approval Date: 7/3/2018
Children's IRB Expiration Date: 5/23/2019

Documentation of Informed Consent and HIPAA Authorization

Research Participant:

_____ _____
Printed Name of Research Subject **Date of Birth**
(If the child to be involved in this research study is a foster child or a ward of the state, please notify the researcher or person obtaining your consent)

_____ _____ _____
Signature of Research Subject **Date** **Time**
(*if 18 years or older)*

Parent/Legal Guardian of Research Participant:

Printed Name of Parent/Legal Guardian:_____

_____ _____ _____
Signature of Parent/Legal Guardian **Date** **Time**
(Required for research subjects under the age of 18 years)

Relationship to child: ☐ Parent ☐ Legal Guardian (state relationship):_____

Researcher:

I have fully explained the research study described in this form, including the risks and benefits. I have answered participant and/or parent questions and will continue to answer future questions to the best of my ability. I will tell the participant and/or family if there are changes to the research procedures or risks and benefits that may impact their health or willingness to stay in the study.

Printed Name of Person Obtaining Consent:_____

_____ _____ _____
Signature of Person Obtaining Assent/Consent/Permission **Date** **Time**

Assent Determination:
☐ The child is 5 years of age or younger and assent is not required for participation in this research study.
☐ The child is between the ages of 6-10 years old and has been verbally assented to participate in this research study.
☐ In my opinion, the child is not able to assent to participate in this research study for the following reason:

Interpreter:

_____ _____ _____
Signature of Interpreter (if applicable) **Date** **Time**

CHOA IRB#: 18-052
Children's IRB Approval Date: 7/3/2018
Children's IRB Expiration Date: 5/23/2019
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