Participant Information and Consent Form

Perioperative multimodal analgesia including intravenous lidocaine infusion for pain management following idiopathic scoliosis correction surgery in children [H18-03103]

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Tel: 604-875-2711

Emergency 24-Hour Contact: 604-875-2161; *Ask to page the anesthesiologist on call*

Non-Emergency Contact: 604-875-2711

If you are a parent or legal guardian of a child who may take part in this study, permission from you and the assent (agreement) of your child may be required. When we say "you" or "your" in this consent form, we mean you and/or your child; "we" means the doctors and other staff.

1. Invitation

You are being invited to take part in this research study because you are undergoing scoliosis correction surgery under general anesthesia at BC Children's Hospital (BCCH).

2. Your participation is voluntary

Your participation is voluntary. You have the right to refuse to participate in this study. If you decide to participate, you may still choose to withdraw from the study at any time without any negative consequences to the medical care, education, or other services to which you are entitled or are presently receiving.

You should be aware that there is a difference for both you and your doctor between being a patient and being a research participant. As a patient, all medical procedures and treatments are carried out for your benefit only according to standard accepted practice. As a research participant, you and your doctor also must take into account the requirements for the research study. These may include procedures and treatments that are not part of standard practice or are not yet proven. This consent form describes the diagnostic and treatment procedures that are being carried out for research purposes. Please review the consent document carefully when deciding whether or not you wish to be part of the research and sign this consent only if you accept being a research participant.

If you wish to participate in this study, you will be asked to sign this form.

Please take time to read the following information carefully and to discuss it with your family, friends, and doctor before you decide.

3. Who is conducting this study?

This study is being conducted by the Pediatric Anesthesia Research Team (PART), a division of the Department of Anesthesia at BC Children's Hospital.

No investigator is receiving any financial compensation from any outside funding agency for conducting or being involved with any part of this study, and there is no possibility of benefit to the investigators from commercialization of any research findings.

4. Background

Many adolescents undergo corrective procedures for scoliosis at BCCH each year. It is the aim of every anesthesiologist to make sure that their patient is as comfortable and calm as possible after the surgery and we use a variety of techniques and medications to achieve this goal.

Multimodal analgesia is the name given to the combination of these techniques and medications for pain management. One medication often given as part of this multimodal therapy is opioids (morphine like drugs) that help control pain. Opioids have a number of

side effects that get worse as higher doses are used. Reducing the amount of opioids needed by using alternate medications (with fewer side effects) and other non-drug techniques is preferred.

One alternative medication of interest is lidocaine, a common local anesthetic used in many procedures including dental work. Lidocaine can be given as an intravenous (IV) infusion and is useful for its analgesic (decreases pain), anti-inflammatory (decreases inflammation), and anti-hyperalgesic (decreases sensitivity to pain) properties. Some studies have shown that, when compared to placebo (an inactive substance used for comparison), lidocaine given as an infusion along with other medications can reduce the amount of pain that patients experience while recovering from their surgeries.

Health Canada has not yet approved the use of IV lidocaine for use in children, although they have allowed its use in this clinical study. Despite this, its use in children undergoing anesthesia is reported in the medical literature and some of the anesthesiologists use lidocaine regularly in children here at BCCH.

5. What is the purpose of the study?

The purpose of this study is to determine if an IV infusion of lidocaine, started during surgery and continued for 48 hours, will reduce the amount of morphine needed after surgery. We also hope to determine if this improves the ability for scoliosis patients to get moving sooner in recovery.

This is a Phase III study. A Phase III study is a study of an experimental drug or treatment which is given to large groups of people to confirm its effectiveness, monitor side effects, compare it to commonly used treatments, and collect information to determine whether the experimental drug or treatment can be used safely.

6. Who can participate in this study?

You may be able to participate in this study if:

- You are between the ages of 10-19
- You have been diagnosed with idiopathic scoliosis
- You are undergoing single-stage posterior spinal instrumentation and fusion (PSIF)

7. Who should not participate in this study?

You will not be eligible to participate in this study if:

- You have pre-existing pain complaints and are on pain medications
- You have a history of seizures
- You have an allergy to lidocaine

- You have heart, liver, or kidney disease
- You have a psychiatric diagnosis such as anxiety, depression, eating disorder, etc. for which you are currently being treated
- You weigh less than the 5th centile for your age, or more than the 85th centile
- You have porphyria

8. What does the study involve?

This study is comparing the 48-hour postoperative morphine use in adolescents undergoing PSIF. Participants will be randomized (like a coin flip) so that they have an equal chance of being placed into one of two groups, those who will receive an IV lidocaine infusion and those who will receive an IV infusion of normal saline (salt water). This process will be double-blinded, meaning that neither the researcher nor participant will know which group they are in.

The hospital pharmacy maintains a record of what a participant receives and will be available to identify the study drug should the need to know arise in an emergency.

All participants receive a standardized multimodal treatment plan, only differing by whether they receive lidocaine or saline infusions. Those who don't participate receive standard management that may be similar to the study but differs by anesthesiologist, and will not include a lidocaine infusion.

The study will last for 48 hours from the start of your surgery and no follow up or additional time will be required to participate. During this time, you will be asked to rate your level of discomfort or pain every 4 hours while awake.

9. What are my responsibilities?

There are no additional responsibilities or requirements necessary for you to participate in this study.

10. What are the possible harms and discomforts?

IV lidocaine therapy in adults is not associated with any significant side effects when used appropriately within therapeutic dose ranges.

At higher doses than we are using in this study, side effects seen in less than 10% of cases include changes in blood pressure, nausea, vomiting, numbness or tingling, dizziness, or a slowed heart rate. Side effects seen in less than 1% of cases include numbness of the tongue or mouth, visual or hearing disturbances, or tremors. Very rare side effects seen in less than 0.1% of cases include allergic reactions, and in very high doses, slowed respiration, double vision, cardiac arrest, and weakness of the limbs.

The safety profile in children is thought to be similar to that observed in adults, although this has not been reported.

11. What are the potential benefits of participating?

No one knows whether or not you will benefit from this study. There may or may not be direct benefits to you from taking part in this study.

We hope that the information learned from this study can be used in the future to benefit other children undergoing PSIF.

12. What are the alternatives to the study treatment?

If you choose not to participate in this study or to withdraw at a later date, your child will receive the standard anesthetic and analgesic medication that is used at BCCH during their procedure and can be given further medication as necessary during recovery. In this case, your anesthesiologist may or may not choose to administer lidocaine intravenously to your child while they are asleep, depending on their usual practice, and whether they feel that it would particularly benefit your child.

You can discuss these options with your doctor before deciding whether or not to participate in this research project.

13. What if new information becomes available that may affect my decision to participate?

If you choose to enter this study and at a later date a more effective treatment becomes available, it will be discussed with you. You will also be advised of any new information that becomes available that may affect your willingness to remain in this study.

14. What happens if I decide to withdraw my consent to participate?

You may withdraw from this study at any time without giving reasons. If you choose to enter the study and then decide to withdraw at a later time, all information about you collected up to the point of your withdrawal will be retained for analysis in order to protect the integrity of the research, which may benefit future research participants and patients. However, no further information will be collected.

15. Can I be asked to leave the study?

If you are not able to follow the requirements of the study or for any other reason, the study doctor may withdraw you from the study and will arrange for your care to continue. On receiving new information about the treatment, your research doctor might consider it to be in your best interests to withdraw you from the study without your consent if they judge that it would be better for your health. If you are asked to leave the study, the reasons for this will be explained to you and you will have the opportunity to ask questions about this decision.

16. How will my taking part in this study be kept confidential?

Your confidentiality will be respected. However, research records and health or other source records identifying you may be inspected in the presence of the Investigator, or his or her designate, by representatives of Health Canada and the UBC C&W Research Ethics Board for the purpose of monitoring the research. No information or records that disclose your identity will be published without your consent, nor will any information or records that disclose your identity be removed or released without your consent unless required by law.

You will be assigned a unique study number as a participant in this study. This number will not include any personal information that could identify you (e.g., it will not include your Personal Health Number, SIN, or your initials, etc.). Only this number will be used on any research-related information collected about you during the course of this study, so that your identity will be kept confidential. Information that contains your identity will remain only with the Principal Investigator and/or designate. The list that matches your name to the unique study number that is used on your research-related information will not be removed or released without your consent unless required by law.

Your rights to privacy are legally protected by federal and provincial laws that require safeguards to ensure that your privacy is respected. You also have the legal right of access to the information about you and, if need be, an opportunity to correct any errors in this information. Further details about these laws are available on request to your study doctor.

Data transferred out of Canada

Sometimes de-identified research data is made publically available so that other researchers can investigate whether the study results are valid. Any study related data sent outside of Canadian borders may increase the risk of disclosure of information because the laws in those countries dealing with protection of information may not be as strict as in Canada. However, all study related data that might be transferred outside of Canada will be coded (this means it will not contain your name or personal identifying information) before leaving the study site. By signing this consent form, you are consenting to the transfer of your information to organizations located outside of Canada.

17. What happens if something goes wrong?

By signing this form, you do not give up any of your legal rights and you do not release the study doctor, participating institutions, or anyone else from their legal and professional duties. If you become ill or physically injured as a result of participation in this study, medical treatment will be provided at no additional cost to you. The costs of your medical treatment will be paid by your provincial medical plan.

In case of a serious medical event, please report to an emergency room and inform them that you are participating in a clinical study and that the following person can then be contacted for further information: Dr. Gillian Lauder at telephone number: 604-875-2711 or

ask to page the anesthesiologist on call at the emergency 24-Hour telephone number: 604-875-2161.

18. What will the study cost me?

All research-related medical care and treatment and any related tests that you will receive during your participation in this study will be provided at no cost to you. There will be no additional cost for you to participate and you will not receive any payment for participation.

19. Who do I contact if I have questions about the study during my participation?

If you have any questions or desire further information about this study before or during participation, or if you experience any adverse effects, you can contact Dr. Gillian Lauder at (604) 875-2711.

20. Who do I contact if I have any questions or concerns about my rights as a participant?

If you have any concerns or complaints about your rights as a research participant and/or your experiences while participating in this study, contact the Research Participant Complaint Line in the University of British Columbia Office of Research Ethics by e-mail at RSIL@ors.ubc.ca or by phone at 604-822-8598 (Toll Free: 1-877-822-8598). Please reference the study number H18-03103 when contacting the Complaint Line so the staff can better assist you.

21. After the study is finished

Study results and publication(s) may be available at the conclusion of the study. Please check the PART website (http://part.bcchr.ca) for information regarding this study and for information on accessing the results.

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Participant Consent

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My signature on this consent form means:

- I have read and understood the information in this consent form.
- I have had enough time to think about the information provided.
- I have been able to ask for advice if needed.
- I have been able to ask questions and have had satisfactory responses to my questions.
- I understand that all personally identifying information collected will be kept confidential.
- I understand that de-identified data may be shared or made publicly available and that the results will only be used for scientific purposes.
- I understand that my participation in this study is voluntary.
- I understand that I am completely free at any time to refuse to participate or to withdraw from this study at any time, and that this will not change the quality of care that I receive.
- I authorize access to my health records as described in this consent form.
- I understand that I am not waiving any of my legal rights as a result of signing this consent form.
- I understand that there is no guarantee that this study will provide any benefits to me.

The parent(s)/guardian(s)/substitute decision-maker (legally authorized representative) and the investigator are satisfied that the information contained in this consent form was explained to the child/participant to the extent that he/she is able to understand it, that all questions have been answered, and that the child/participant assents to participating in the research.

I will receive a signed copy of this consent form for my own records.

I consent to participate in this study.

Participant's Name			
Participant/Parent/Guardian Signature	Printed Name		Date
Signature of person obtaining consent	Name of person obtaining consent	Study Role	Date