Participant Information and Consent Form

Intra-nasal Dexmedetomidine for children undergoing MRI imaging

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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 having a planned MRI procedure at BC Children's Hospital (BCCH), requiring general anesthesia.

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), the research division of the Department of Anesthesia at BCCH.

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 children undergo general anesthesia for many types of procedures, including MRI, at BCCH each year. It is the aim of every anesthesiologist to make sure that their patient is as comfortable and calm as possible and we use a variety of techniques and medications to achieve this goal.

One particular medicine, called dexmedetomidine, is a useful medication that helps with sedation and recovery. Specifically, it provides sedation without affecting breathing and

reduces agitation during waking up. It also reduces shivering, which can happen after some anesthetics.

Side effects of dexmedetomidine include a decrease in blood pressure (hypotension), a slowing of the heart rate (bradycardia), and dry mouth. Because dexmedetomidine is given when the anesthesiologist is closely monitoring the heart rate and blood pressure, these side effects can be easily detected and treated. These side effects are also true for many of the anesthetic drugs given routinely.

Health Canada has not yet approved the use of dexmedetomidine for use in children, although they have allowed its use in this clinical study. Despite this, its use in children undergoing anesthesia is widely reported in the medical literature. Many of the anesthetists use dexmedetomidine regularly in children here at BCCH and report that these effects, if seen at all, are usually short-lived and of no consequence.

You should understand that you may receive dexmedetomidine as part of your routine anesthesia care, (whether or not you take part in this study) if your anesthesiologist thinks you would benefit from it.

5. What is the purpose of the study?

We wish to examine whether dexmedetomidine, delivered as a nasal spray, can be used as the sole agent in aiding the successful completion of a MRI scan in children.

6. Who can participate in this study?

You may be able to participate in this study if you*:*

- Are scheduled for a planned MRI scan
- Are planned to have a general anesthetic
- Between 3-19 years of age

7. Who should not participate in this study?

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

- Are taking existing opioid, sedative, or cannabinoid medication
- Have severe learning difficulties making simple commands difficult to follow
- Have severe cardiac disease or chronic hypertension
- Have an allergy to dexmedetomidine
- Are pregnant

8. What does the study involve?

The study is taking place in the MRI procedure rooms (PRs) of BCCH. We will recruit approximately 180 participants.

If you agree to be in the study, you will prepare for your MRI as you normally would. Once at the hospital, the procedure will also run as it normally would, with the follow differences:

- Following the pre-procedure assessment by the anesthetist, an observer will make note of the level of anxiety displayed by your child.
- A nurse will deliver the dexmedetomidine by a nasal spray into each nostril.
- An intravenous (IV) will not be placed.
- Should your child move during the MRI scan, they will be encouraged to lie still. If however a scan is unsuccessful, an IV will be placed and the scan will be completed under general anesthesia as is routine.

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?

The most common IV-administered, dexmedetomidine-related adverse events reported in adults are low blood pressure (28%), high blood pressure (16%), nausea (11%), and a slowed heart rate (7%). These effects are usually brief and rarely require treatment. Other side effects include a dry mouth, but this is rarely troublesome. There is no information on its effects on pregnancy. The safety profile in children is thought to be similar to that observed in adults, although this has not been reported. Nasal administration may feel slightly uncomfortable but adverse events have 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 an MRI scan.

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 dexmedetomidine 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

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. Mark Ansermino at telephone number: 604-875-2711.

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. Mark Ansermino 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 H18-02794 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

Intra-nasal Dexmedetomidine for children undergoing MRI imaging

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