CHILDREN'S & WOMEN'S HEALTH CENTRE OF BRITISH COLUMBIA

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PARTICIPANT INFORMATION AND CONSENT FORM

Anesthetic sparing effect of dexmedetomidine during TIVA with propofol and remifentanil for children undergoing dental procedures

Principal Investigator

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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.

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

Non-Emergency Contact: 604-875-2711

INVITATION

You are invited to participate in this study because your child is undergoing a procedure under general anesthesia at BC Children's Hospital (BCCH).

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.

Before you decide, it is important for you to understand what the research involves. This consent form will tell you about the study, why the research is being done, what will happen to you during the study and the possible benefits, risks and discomforts.

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.

Please take time to read this information and ask any questions that may help you understand the study before you decide whether to participate.

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

WHO IS CONDUCTING THIS STUDY?

The study is being conducted by the principal investigator, Dr. Simon Whyte, who is a staff pediatric anesthesiologist, in collaboration with Dr. Randa Ridgway who is a pediatric anesthesiology fellow, Andrew Poznikoff who is a staff research coordinator, and Dr. Matthias Görges who is an engineering scientist. All four of these investigators are members of the Pediatric Anesthesia Research Team (PART – part.bcchr.ca).

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.

BACKGROUND

Many children undergo general anesthesia for procedures 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.

One particular medicine, called dexmedetomidine, is a useful medication that helps with many aspects of the recovery. Specifically, it provides pain relief while reducing agitation during waking up. It also reduces shivering, which can happen after some anesthetics. Another benefit of dexmedetomidine is that it reduces the use of medication with agents in the morphine family (opioids), which are associated with side-effects like excessive sedation, nausea and vomiting and decreased breathing.

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 during the operation, 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 during surgery.

Like many drugs, dexmedetomidine has not yet been approved for use in children. 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.

WHAT IS THE PURPOSE OF THE STUDY?

We wish to examine whether dexmedetomidine allows for a reduction in the amount of other medications required during a procedure.

WHO CAN PARTICIPATE IN THE STUDY?

Your child may be eligible to participate in this study if:

- Your child is between 2 and 10 years old
- Your child is having elective dental surgery
- Your anesthesiologist thinks that giving you dexmedetomidine is appropriate

WHO SHOULD NOT PARTICIPATE IN THE STUDY?

Your child will not be eligible to participate in this study if:

- Your child has cardiac disease or rhythm abnormalities
- Your child has a seizure disorder or previous brain surgery
- Your child has chronic hypertension
- Your child is allergic to dexmedetomidine

WHAT DOES THE STUDY INVOLVE?

The study is taking place in the procedure rooms (PRs) of BCCH. We will recruit at least 88 participants.

If you agree to be in the study, we will randomly place your child into one of four different groups:

- Group 1 will receive a small volume (10mL) of normal saline solution
- Group 2 will receive a dose of 0.25 mcg/kg dexmedetomidine
- Group 3 will receive a dose of 0.50 mcg/kg dexmedetomidine
- Group 4 will receive a dose of 1.00 mcg/kg dexmedetomidine

The doses of dexmedetomidine chosen for this study were selected by an experienced anesthesiologist, and are all considered to be within a safe and appropriate clinical range.

Some anesthesiologists at BCCH routinely give dexmedetomidine for procedures as they deem appropriate, other anesthesiologists do not routinely use dexmedetomidine. Therefore some patients may not be getting dexmedetomidine if they were not enrolled in the study while others may receive dexmedetomidine regardless of participation. However, the study has been discussed with all of the BC Children's Hospital anesthesiologists and all have agreed that they are comfortable administering the dexmedetomidine doses as the study requires. If your anesthesiologist does not feel that dexmedetomidine is appropriate for your child, then they will discontinue the study and carry on their anesthetic as usual.

All study procedures will happen in the PR, once your child has gone to sleep.

The only difference between a usual anesthetic given and this study is the administration of the study medicine, dexmedetomidine, at one of the three pre-defined doses, or a small infusion of normal saline solution to mimic the effect of giving the drug if you are in the control group (Group 1). During your procedure, the anesthesiologist will monitor your depth of anesthesia using a Bispectral Index (BIS) monitor, which is a non-invasive sensor that is put on the forehead. There will be minimal delay in starting your operation as a result of this study.

The amount of medication your child will receive to keep them asleep will be dictated by the BIS monitor, which is a safe and effective way to determine how much anesthetic your child actually needs. The anesthetist will be monitoring your child's blood pressure, heart rate and regularity throughout the entire procedure, as they normally would.

WHAT ARE MY RESPONSIBILITIES?

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

WHAT ARE THE POSSIBLE HARMS AND DISCOMFORTS

The most common dexmedetomidine-related adverse events reported in adults in a post-surgical setting are hypotension (28%), hypertension (16%), nausea (11%), and bradycardia (7%). These effects are usually brief and rarely require treatment. They are more frequently seen when the medicine is given in larger doses, rapidly. Other side effects include a dry mouth, but this is rarely troublesome. The safety profile in children is thought to be similar to that observed in adults, although it has not been systematically reported.

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 children receiving this medication and anesthesiologists looking after them when they have their surgery.

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. Your anesthesiologist may or may not choose to administer dexmedetomidine to your child while they are asleep, depending on their usual practice, and whether they feel that it would particularly benefit your child for the procedure that they are having. You can discuss this with your anesthesiologist before deciding whether or not to participate in this research project.

WHAT IF NEW INFORMATION BECOMES AVAILABLE THAT MAY AFFECT MY DECISION TO PARTICIPATE?

If you choose to enter this study and at a later time 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.

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 data collected about your child during your enrollment in the study 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.

CAN I BE ASKED TO LEAVE THE STUDY?

If there is some reason that it is not appropriate for your child to receive the medication, the study doctor may withdraw you from the study and will arrange for your care to continue. On receiving new information about your child's health or response to the anesthetic medications given, your study 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.

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 your child may be inspected in the presence of the Investigator or her/his designate by representative, and the UBC C&W Research Ethics Board for the purpose of monitoring the research. No information or records that disclose your child's 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. Any data that is required to be reported as a result of

publishing project findings, or that might be useful in future studies, will be de-identified and unable to be linked back to you.

Your child will be assigned a unique study number as a participant in this study. This number will not include any personal information that could identify your child (eg. it will not include your child's Personal Health Number, SIN, or initials, etc.). Only this number will be used on any research-related information collected about your child during the course of this study, so that their identity will be kept confidential. Information that contains your child's identity will remain only with the Principal Investigator and/or designate. The list that matches your child's name to the unique study number that is used on their 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 insure that your privacy is respected. You also have the legal right of access to the information about you that has been provided to the sponsor 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.

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 your child becomes 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 child's medical treatment will be paid by your provincial medical plan and/or by the study sponsor.

WHAT WILL THE STUDY COST ME?

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

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 your participation, you can contact Dr Whyte at 604-875-2711.

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 (H17-02157) when contacting the Complaint Line so the staff can better assist you.

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 participant information and 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 had the opportunity to ask questions and have had satisfactory responses to my questions.
- I understand that all of the information collected will be kept confidential and that the results will only be used for scientific purposes.
- I understand that my participation in this study is voluntary and that I am completely free to refuse to participate or to withdraw from this study at any time without changing in any way the quality of care that I receive.
- I understand that I am not waiving any of my legal rights as a result of signing this consent form.

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 Name

_____
Parent/Guardian Signature Printed Name Date

_____
Signature of Person Obtaining Consent Printed Name Study Role Date