



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

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SUBJECT INFORMATION AND CONSENT FORM

Title of Study: Skin conductance fluctuations and heart rate variability
as measures of intraoperative nociception in children

Principal Investigator:

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Emergency Telephone Number: 604-875-2161. Ask to page the anesthesiologist on call. This number is available 24 hours a day, 7 days a week.

1. INTRODUCTION

You are being invited to have your child take part in this research study because he/she will be undergoing surgery. The aim of our research is to improve the detection of inadequate anesthesia during surgery in children.

2. YOUR PARTICIPATION IS VOLUNTARY

Your child's participation is entirely voluntary, so it is up to you to decide whether or not to have your child participate. 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 your child during the study, and the possible benefits, risks, and discomforts associated with the study.

If you do decide to have your child participate, you will be asked to sign this form. You are still free to withdraw at any time and without giving any reason for your decision.

If you do not wish to have your child participate, you do not have to provide any reason for your decision not to have your child participate, nor will your child lose the benefit of any medical care to which they are entitled or are presently receiving.

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 THE STUDY?

The study is being conducted by Dr. Carlyne Montgomery and Dr. Mark Ansermino, both of whom are pediatric anesthesiologists working at British Columbia Children's Hospital. Ms. Joanne Lim, Mr. Eugene Choo, Mr. Chris Brouse, and Mr. William Magruder, researchers with the Department of Anesthesia, are also involved in the study. The Principal Investigator has not received any financial compensation from any funding agency for enrolling subjects in this study.

4. BACKGROUND

Your child may require pain medication during surgery to reduce the amount of pain that he or she experiences. We are trying to find ways to measure and treat pain in children. Doctors have traditionally based their treatment on a child's verbal self-reporting of pain after surgery. However, effective treatment of pain while under anesthesia becomes difficult as your child is unable to express the intensity of pain that he or she is experiencing.

Inadequate anesthesia ("light anesthesia") may be caused by insufficient pain or sleeping medicine. Rarely, movement, and extremely rarely, awareness may occur during certain surgical procedures. Our current practice is to watch your child's blood pressure, heart rate and breathing and more recently, brain wave function. Based on changes in these, the anesthesiologist adjusts the amount of sleeping and pain medicine that is given. During the procedure, the amount of sleeping and pain medicine required will change depending on what the dentist or surgeon is doing. A device to help us to make these decisions may improve our anesthetic care.

When children experience pain, the electrical activity in their skin changes, as does their heart rate. We are trying to find a particular measurement of electrical activity in the skin that will tell us that a child is experiencing pain. We are also trying to link changes in heart rate to pain. This would alert doctors that the child should receive further pain relief medication. The requirements for pain medication vary a great deal between children. Being able to tell whether a child is experiencing pain would help us avoid giving too much or too little medication. We are using a device (MedStorm) to measure these changes in electrical activity.

The MedStorm device we are using in this study is an investigational device that is approved by Health Canada and has been used in a previous study by our group looking at pain levels after surgery.

5. WHAT IS THE PURPOSE OF THE STUDY?

The purpose of this study is to find out whether changes in sweating in the skin (a measure of changes in electrical activity in the skin), and changes in heart rate, can accurately assess the intensity of a child's pain during surgery.

Improved awareness of the level of pain will allow us to give pain relief medication more effectively. This can improve your child's pain management during and after surgery.

6. WHO CAN PARTICIPATE IN THE STUDY?

In order to participate in this study, your child must be between 3 and 6 years old, be in good general health, and be scheduled for dental surgery under general anesthesia.

7. WHO SHOULD NOT PARTICIPATE IN THE STUDY?

Children with cardiorespiratory (heart/lung) disease or other major health problems should not participate in this study. Children who are sensitive to the drugs propofol and remifentanyl should not participate. Children who have skin problems or are taking medications that will interfere with the monitors cannot participate. Your child's anesthesiologist will be able to determine if your child should not participate.

8. WHAT DOES THE STUDY INVOLVE?

If you agree to take part in this study, the procedures you can expect will include the following:

Before surgery

Your child's heart rate, blood pressure, and rate of breathing will be measured. These measurements are routinely performed. We will also measure your child's skin temperature using a standard temperature probe.

During surgery

Your child will have stickers for three separate monitoring devices: 1) brain wave monitor which is applied to the forehead; 2) muscle contraction (which are applied to the wrist and arm; and the 3) Medstorm which are applied to the palm of the hand. The research assistant will show you these stickers.

We will measure how deeply asleep your child is with a sticker on their forehead (that measures brain waves). The reading from these stickers may help guide the anesthesiologist on how much sleeping medication to give during the procedure. These stickers are not yet in routine use for the procedure your child is receiving but are in common use for other procedures at BC Children's Hospital.

Your child will also have stickers on the palm of their hand that will measure the electrical activity in the skin (MedStorm device). While your child is asleep, we will cause the muscles in the hand to contract using electrodes (stickers on their wrist and arm). This kind of stimulation is commonly used when trying to find out how well muscle blocking drugs are working. We will measure the response of your child to this stimulation while deeply asleep. We will measure the response of your child to changes in their breathing pattern while they are having their surgery.

Other than the stickers mentioned above, the care your child receives will not differ from common practice.

Your child will be deeply asleep before any of these additional measurements are performed.

This study will be performed during surgery. You will not need to make any additional trips to the hospital.

9. WHAT ARE MY RESPONSIBILITIES?

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

10. WHAT ARE THE POSSIBLE HARMS AND SIDE EFFECTS OF PARTICIPATING?

Unanticipated changes in heart rate, breathing, and blood pressure during the muscle contraction stimulation may require extra pain and sleeping medicine. The amount of

sleeping and pain medicine your child will be receiving during this test is designed to minimize the chance of this happening but as every child's pain and sleeping medicine requirement is different, we have designed the study to make the chance of this happening as small as possible without giving your child too much sleeping or pain medicine. Should your child show any of the signs of "light anesthesia", the study requires the doctors to give more sleeping and pain medicine.

The stickers might leave slight red marks on your child's forehead, hand, and arm due to the adhesive. These marks usually disappear within one hour.

11. WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?

There will be no direct benefits to you or your child resulting from your child's participation in this study. There is no financial reimbursement or other reward for participation.

The information we obtain from the study may be used to advise anesthesiologists on the usefulness of monitoring electrical activity in the skin and heart rate changes as a way of measuring pain in patients during surgery. This study could lead to more effective pain management in children.

12. WHAT ARE THE ALTERNATIVES TO THE STUDY TREATMENT?

If not enrolled in the study, your child will undergo their surgery as scheduled with all anesthesia, pain relief, and surgery exactly as they would under routine circumstances.

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

If new information arises during the research study that may affect your or your child's willingness to remain in the study, you and your child will be advised of this information. You and your child will be advised if risks are identified in relation to your child's participation in the study.

14. WHAT HAPPENS IF I DECIDE TO WITHDRAW MY CONSENT TO PARTICIPATE?

Your child's participation in this research is entirely voluntary. You may withdraw your child from this study at any time without explanation. Your withdrawal does not need to be in writing. The study investigators may decide to discontinue the study at any time, or withdraw you from the study at any time, if they feel that it is in your child's best interest. If you decide to enter your child in the study and withdraw at any time in the future, there will be no penalty or loss of benefits to which you and your child are otherwise entitled,

and your child's future medical care will not be affected. If you choose to enter the study and then decide to withdraw at a later time, all data collected about your child during his/her enrolment in the study will be retained for analysis; by law, this data cannot be destroyed.

15. WHAT HAPPENS IF SOMETHING GOES WRONG?

Signing this consent form does not limit your or your child's legal rights against the investigators or anyone else.

16. CAN I BE ASKED TO LEAVE THE STUDY?

The study investigators may decide to discontinue the study at any time, or withdraw your child from the study at any time, if they feel that it is in your child's best interest.

17. AFTER THE STUDY IS FINISHED

The results of the study will be submitted to a relevant journal read by anesthesiologists all over the world. This may take up to 1 year after the study is completed.

18. WHAT WILL THE STUDY COST ME?

There will be no additional cost to you for your child's participation in the study. You will not be charged for any research procedure.

You will not be paid for participating in this study.

19. WILL MY CHILD'S PARTICIPATION IN THIS STUDY BE KEPT CONFIDENTIAL?

Your child's confidentiality will be respected. No information that discloses your child's identity will be released or published without your specific consent to the disclosure. However, research records and medical records identifying your child may be inspected in the presence of the Investigator or his or her designate by representatives of Health Canada or the UBC C&W Research Ethics Board for the purpose of monitoring the research. However, no records that identify your child by name or initials will be allowed to leave the Investigators' offices.

20. 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 child's participation, you can contact Dr. Carlyne Montgomery at 604-875-2711.

**21. WHO DO I CONTACT IF I HAVE ANY QUESTIONS OR CONCERNS
ABOUT MY CHILD'S RIGHTS AS A SUBJECT DURING THE STUDY?**

If you have any concerns about your child's rights as a research subject and/or their experiences while participating in this study, please contact the Research Subject Information Line at the University of British Columbia's Office of Research Services at 604-822-8598.

SUBJECT CONSENT TO PARTICIPATE

I have read or have had read to me all of the above. I have had sufficient time to consider the information provided and to ask for advice if necessary. 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 objectives. I understand that my child’s participation is voluntary and that he/she may refuse to participate, or I may withdraw my child from the study at any time without changing in any way the quality of care they receive. 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 my child. I have read this form and I freely consent for my child to participate in this study.

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

I have been told that I will receive a dated and signed copy of this form.

Subject’s name: _____

Printed name of subject’s parent / Legally acceptable representative	Signature	Date
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Printed name of principal investigator/ Designated representative	Signature	Date
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Printed name of translator (if applicable)	Signature	Date
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