



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

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SUBJECT INFORMATION AND CONSENT FORM

Title of Study:

Comparison of an automated calculation of capillary refill time (CRT) with a standard clinical measurement in children with an abnormal CRT

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1. INTRODUCTION

You are invited to have your child participate in this study because he/she is a patient on the Intensive Care Unit. We are investigating two different ways of measuring capillary refill time (CRT) (amount of time for blood to return to the finger after being squeezed).

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.

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 reasons for your decision.

If you choose not to be involved or to withdraw your child from the study, you do not have to tell us why. The medical care that your child will be receiving will not be any different or less than the care he/she would normally receive. Please take time to read this information and ask any questions that may help you understand the study before you decide whether to be in the study or not.

3. BACKGROUND

Capillary refill time (CRT) is the time taken for blood to refill the capillaries (eg. small blood vessels at the end of your finger). CRT can be measured by pressing a fingernail until it turns white, and measuring the time needed for colour to return once the nail is released (normal time is 2 seconds or less). The measurement of CRT is an important part of the clinical assessment of both adults and children.

Any test used to make treatment decisions must be accurate and reproducible. Currently the major drawback of CRT measurement is that it is not reliably reproduced between different people (eg. if one person measures CRT to be a particular number, someone else may measure a different number). This can be due to the amount of pressure and/or time the person presses the finger.

There is currently no reliable method of measuring CRT. This study aims to provide a simple to use method which will eliminate the poor reliability of the CRT test and eventually help healthcare workers in developing countries use the CRT test.

4. WHY IS THIS STUDY BEING DONE?

This study will help us to compare standard measurements of CRT with an automatic calculation of CRT.

5. WHO CAN PARTICIPATE IN THE STUDY?

In order to participate in the study, your child must be aged from 1 day to 6 years and a patient on the ICU.

6. WHO SHOULD NOT PARTICIPATE IN THE STUDY?

There are no subjects who cannot be part of this study.

7. WHAT DOES THE STUDY INVOLVE?

The study is taking place in the ICU of British Columbia Children's Hospital. We will recruit 50 subjects.

We will apply pressure to your child's finger using two methods to measure CRT. One will be the standard method of manually squeezing the index/pointer finger. We will use a stopwatch to time how long it takes for the color to return to the fingernail. The second method will be applying pressure to the finger over the oxygen monitor on your child's finger; we will do this first manually and then using a reproducible pressure on the finger and using automatic calculations to measure CRT. We will repeat each measurement 3 times. These measurements will take 5-10 minutes in total.

Your child's gender, weight and age will be recorded and will be kept secure and anonymous.

8. WHAT ARE THE POTENTIAL RISKS INVOLVED WITH PARTICIPATION?

There are no additional risks from participating in this study.

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

There are no direct benefits to your child's participation in this study. The information we obtain from the study will be used to advise doctors in the future about CRT measurements. There is no financial reimbursement for participation.

10. 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. 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.

11. WHAT ARE MY LEGAL RIGHTS?

Signing this consent form in no way limits your legal rights against the sponsor, investigators, or anyone else.

12. CAN MY CHILD BE ASKED TO LEAVE THE STUDY?

The study doctor(s)/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 interests.

13. WHAT WILL THE STUDY COST ME?

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

14. 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.

Research records and medical records identifying your child may be inspected, in the presence of an Investigator or his or her designate, by representatives of the UBC Research Ethics Boards, for the purpose of monitoring the research. However, records which identify your child by name or initials will be kept in a locked cabinet and will not be allowed to leave the Investigators' offices. Copies of relevant data, which identify your child only by code number, may be required by regulatory agencies. However, your child will not be identified by name, initials, or date of birth as part of this study data.

15. WHO DO I CONTACT IF I HAVE QUESTIONS ABOUT THE STUDY DURING MY CHILD'S PARTICIPATION?

If you have any questions or desire further information about this study before or during your child's participation, you can contact Dr. Ansermino at 604-875-2711.

16. 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 treatment rights as a research subject, please contact the Research Subject Information Line at the University of British Columbia Office of Research Services at 604-822-8598 or if long distance e-mail to RSIL@ors.ubc.ca.

17. CONSENT TO PARTICIPATE

I have read or have had read to me all of the above. I have had enough time to consider entry to the study. All of my questions have been answered to my satisfaction. I understand that my child's participation is entirely voluntary and that he/she may refuse to participate, or I may withdraw my child from the study at any time.

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 acknowledge having received a signed and dated copy of this consent form for my own records.

Name of Subject: _____

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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