Study Title: Advanced Wireless Sensors for Neonatal Care in the Delivery Room: the AWARD Prospective Multicenter International Study - AWARD Project – Clinical Study.

STUDY ICF - HCPs

22 April 2024

Centre universitaire de santé McGill
McGill University Health Centre

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FMU-9997

ADDRESSOGRAPH

L'Hôpital de Montréal pour enfants
The Montreal Children's Hospital
Centre universitaire de santé McGill
McGill University Health Centre

INFORMATION AND CONSENT FORM

Study Title: Advanced Wireless Sensors for Neonatal Care in the Delivery Room: the AWARD Clinical Study: Health-Care Practitioner Survey

MUHC Study Code: 2025-10687

Principal Investigator: Guilherme M. Sant'Anna MD, PhD, FRCPC, Associate Professor of Pediatrics, Neonatal Division, Montreal Children's Hospital, Research Institute of the MUHC**.**

Co-Investigator: Wissam Shalish MD, PhD, Assistant Professor of Pediatrics, Neonatal Division, Montreal Children's Hospital, Research Institute of the MUHC.

Department/Division: Department of Pediatrics/Neonatology

Study Sponsor: Research Institute of the McGill University – Dr Guilherme Sant'Anna

Funding provided by the Montreal Children's Hospital Foundation

WHY ARE YOU BEING INVITED TO TAKE PART IN THIS STUDY?

The pediatric/neonatology department participates in research studies to improve the feasibility, accuracy, and safety of vital sign monitoring of newborn babies. Today, we are inviting you to participate in a research study because you are a healthcare practitioner involved in the care of a neonate participating in this study.

This research study will use a new wireless skin chest sensor called the AnneARC™(SIBEL Health Inc, Illinois, USA) and a wireless limb sensor called Radical-7 (Masimo, California, USA) and compare it to the standard of care vital sign monitor system which is attached to the body using wires, called the Infinity® M540 (Dräger, Lubeck, Germany). Both vital sign monitoring systems will be tested simultaneously on newborn babies immediately after birth. The wired vital sign monitor system is considered the standard of care for continuous monitoring of newborn babies in the delivery room and the neonatal intensive care unit.

Please read this information to help you decide if you want to participate in this survey. In participating in this study, it is important that you understand what is involved, including potential risks and benefits. We invite you to speak to the doctor responsible for this study or to other members of the research team and ask them any questions you may have about this study. Please also ask a member of the research team about any parts of this consent form you do not understand.

If you agree to participate in this survey, you will be asked to sign this informed consent form. Please take all the time you need to make your decision. You may also discuss this with your friends, colleagues and family.

WHY IS THIS STUDY BEING DONE?

This structured survey is being conducted to help assess the feasibility of wireless monitoring systems compared to that of standard wired monitoring systems. This survey aims to obtain the opinions and satisfaction rates of healthcare practitioners who are involved in the care of an infant participating in the AWARD Clinical Study and being monitored with the wireless skin sensor system and the standard of care wired monitoring systems.

The purpose of this study is to understand if the Anne Arc™ wireless, non-invasive skin sensor is an accurate, safe, and reliable method for assessing the vital signs of healthy newborn babies.

We aim to compare the wireless skin sensors with traditionally used wired skin sensors and electrodes to determine its effectiveness in monitoring heart rate, breathing rate, oxygen saturation, and skin temperature of healthy newborns.

We are interested in exploring the potential benefits of integrating wireless sensors into delivery room facilities, as this may allow for continuous monitoring of vital signs. Such continuous monitoring can contribute to the promotion of safe Kangaroo Mother Care (skin-to-skin contact) and, importantly, may serve as a preventive measure against catastrophic events like respiratory arrest, cardiac arrest, and sudden unexpected postnatal collapse. Your participation in this study will help us measure how feasible, safe, and accurate ANNE Arc™ is for healthy newborn babies, which can also help us assess its potential as a valuable tool in ensuring the well-being of newborns.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

We will recruit 100 health care professionals who are part of the circle of care of mothers and infants participating in the AWARD Clinical study during delivery and the first 2hrs after birth.

WHAT WILL HAPPEN IN THIS RESEARCH STUDY?

You will be asked to complete a short, de-identified survey about your experience using the wireless skin sensors (ANNE Arc™ and Radical-7) , compared to the standard wired system, in the delivery room setting. The survey is designed to capture your honest opinions and any feedback regarding the feasibility, usability, and satisfaction with both types of monitoring systems. It is expected to take approximately 5-10 minutes of your time. The survey questions will cover various aspects of the wireless skin sensor monitoring systems in an aim to assess your overall satisfaction.

WHAT ARE THE RISKS?

Participation in this survey involves minimal risk to you as a healthcare practitioner. You and your patients' identity will remain confidential. In order to be able to cross analyze the results of the survey the study identification code of the patient will be used on the survey, as well your professional role. However, the survey does not request any personal information that can be used to identify you. All data will be securely stored and only accessible to the research team. Any publications resulting from this study will be presented in aggregate form only, with no possibility of identification of individual responses.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

There is no direct benefit from enrolling in this study. However, the results of this study may help doctors find better and more effective ways to continuously monitor babies' health after birth.

IS ANY COMPENSATION BEING OFFERED?

You will receive a 25$ gift card as compensation for participating in this study.

HOW IS PRIVACY ENSURED

All study data collected during this research study (including personal information) will remain confidential to the extent provided by law. No personal information will be collected or linked to the survey responses.

For the purposes of correlating the survey data with clinical outcomes, the only information the research team requires is the study code of the newborn whose care you were responsible for during the use of the monitoring systems being evaluated in this study. This code will be used solely for tracking responses and will not be used to identify you as a respondent. Your honest and uninhibited feedback is essential, and your anonymity will be maintained throughout the research process.

As part of this research study to improve the quality, accuracy, and efficiency of monitoring neonates after birth, deindentified, anonymized, and/or aggregated data collected from your participation in the study may be shared with other academic or commercial third parties involved in this Study under the Smart Hospital Project, including SIBEL Health Inc., Northwestern University, iKinesia Inc., Drager, and

Masimo. By signing this form, you are consenting and giving the research study team permission to share your survey responses with academic and commercial third parties for the purposes of this research study. All required data sharing agreements will be in place prior to releasing your data to any third party.

The study data may be published or shared at scientific meetings; however, it will not be possible to identify you.

If information from this study is published or presented at scientific meetings, your name or other personal information will not be used.

The Principal Investigator is responsible for securely storing all the research data for 15 years in a locked office or in a password protected file on a secure sever.

WHAT ARE THE COSTS OF TAKING PART IN THIS STUDY?

There are no associated costs of taking part in this study.

IS YOUR PARTICIPATION VOLUNTARY?

Taking part in this study is entirely voluntary. You may choose whether or not to participate in this study without any impact on your current or future relationship with the RI-MUHC or the research team. You can withdraw from the study at any time, for any reason, without consequence.

Should you choose to withdraw from the study no additional data will be collected, but all data collected up until the date of your withdrawal will continue to be used for the purposes of the research study in order to maintain the integrity of the study.

The doctor in charge of this study or the Research Ethics Board may put an end to your participation without your consent. This may happen if new findings or information indicate that participation is no longer in your interest, if you do not follow study instructions, or if there are administrative reasons to terminate the project.

POSSIBILITY OF COMMERCIALIZATION

The results of the research derived in part from your participation in the study may lead to the development of new commercial products. However, you will not be entitled to any financial gain thereof.

CONFLICT OF INTERESTS

The researchers have no conflict of interest to declare.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

If you have any questions about this research project, please feel free to contact Dr. Guilherme Sant'Anna (514) 412-4400 (ext. 23489) or Dr. Wissam Shalish (ext. 22341).

If you have any questions concerning your rights as a research participant or want to file a complaint, please contact the patient representation (ombudsman) at the Royal Victoria Hospital , 514-934-1934

ext. 35655.

OVERVIEW OF ETHICAL ASPECTS OF THE RESEARCH

The Research Ethics Board of the McGill University Health Center reviewed this project and will be responsible for the research ethics oversight of the project.

CONSENT FORM

Title of this research project: Advanced Wireless Sensors for Neonatal Care in the Delivery Room: the AWARD Clinical Study: Health-Care Practitioner Survey

I have reviewed the Informed Consent form. Both the research study and the Informed Consent form were explained to me. My questions were answered, and I was given sufficient time to make my decision. After consideration, I consent to participate in this research study in accordance with the conditions stated above.

I understand that the survey responses are anonymous and that no personal data will be linked to my survey responses. The only piece of information required is the baby's study code to correlate the survey data with clinical outcomes.

I understand that my participation in this study is voluntary, and I am free to withdraw at any time without consequence.

I authorize a member of the research study to communicate with me to see if I am interested in participating in other research studies.

Yes ☐ No ☐ If yes, please provide contact information: _____

Name of participant (Print)	Signature	Date

I have explained to the participant all the relevant aspects of this study. I answered any questions they asked. I explained that participation in a research project is free and voluntary and that they are free to stop participating at any time they choose.

Name of Person obtaining consent (Print)	(signature)	Date