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

STUDY ICF - PARENTS

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: Parent Consent

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

In this research informed consent form, "You" means "you/your child."

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 ≥ 35 weeks pregnant and are having a normal, low risk pregnancy, and your baby is healthy.

Most babies born are healthy and do not require any interventions after delivery. However, some babies may not breathe properly when born and require resuscitation in the delivery or during unsupervised Kangaroo Mother Care (skin to skin contact), a practiced that is beneficial for bonding and breastfeeding. Currently, 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 but is not used after birth unless a baby requires resuscitation.

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 as heart rate, temperature, respiratory rate, and oxygen saturation. Wireless vital sign monitoring may contribute to the promotion of safe Kangaroo Mother Care (skin-to-skin contact) and may prevent catastrophic events like respiratory arrest, cardiac arrest, and sudden unexpected postnatal collapse saving babies' lives.

Please read this document carefully to help you decide if you want to participate in this research study. It is important that you understand what is involved if you decide to participate in this research study, 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 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 study, 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 and family, or your baby's physician.

WHY IS THIS STUDY BEING DONE?

This research study will use a new wireless skin chest sensor called the Anne ARC™ (SIBEL Health Inc, Illinois, USA) and a wireless limb sensor called Radical-7® Pulse CO-Oximeter®
(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 purpose of this study is to understand if the Anne Arc™ and Radical-7® Pulse CO-Oximeter®wireless, non-invasive skin sensors are accurate, safe, and reliable method for assessing the vital signs of healthy newborn babies.

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?

100 newborn babies will take part in this study at the McGill University Health Centre. This is a multi-site study that is also taking place in 5 other hospitals in South America and Africa. A total of 600 babies will be recruited to this study, approximately 100 babies from each participating hospital.

WHAT WILL HAPPEN IN THIS RESEARCH STUDY?

Your baby's care will not be affected by participating in this research study. If you decide to participate in this study, you are agreeing to the following:

- The ANNE Arc™ wireless chest sensor and the Radical-7® Pulse CO-Oximeter® limb sensor will be placed on your baby immediately after birth. If you give birth via C-section: The research team will randomly decide which type of monitoring system will be applied first, traditional wired system (Dräger) or AnneArc™ and Radical-7® Pulse CO-Oximeter®.
- The ANNE ARC™ wireless monitoring sensor will be placed on your baby's chest to measure heart rate, respiratory rate and temperature, and the Radical-7® Pulse CO-Oximeter® wireless sensor will be placed on your baby's leg to measure oxygen saturation (SpO_2 - how well blood is delivering oxygen to your baby's body.). These sensors are non-invasive, small, soft, and light.
- 10-20 minutes after your baby is born and you have had a chance to hold and interact with your baby, a member of the research team will attach the traditional wired system which consists of wired ECG skin sensors placed on your baby's chest to measure heart rate, a wired skin sensor placed under your baby's arm to measure temperature, and a standard wired pulse oximetry wrapped around your baby's limb to measure oxygen saturation.
- Your baby will be continuously monitored by both systems at the same time for 2 hours. You and your healthcare team will be able to continue to provide regular care to your baby during the monitoring period. Research team members (maximum 2) will be in the room to record and take notes while the monitoring takes place and will remove both systems from your baby after the 2-hour recording period.
- A research team member will take photographs of the skin before placing and after removing the skin sensors. The photographs will be sent to a dermatologist, a medical doctor who specializes in conditions that affect the skin, hair, and nails, for review to determine if any of the skin sensors caused any problems to your baby's skin. Any images sent will not show your baby's face and will only have your baby's study code to ensure your baby's privacy.
- A research team member will also perform a quick assessment to ensure that the removal of the sensor, adhesives and probes is not causing pain or discomfort to your baby.
- The research team will collect medical information about you and your baby from your respective medical charts. This information will be de-identified. Only information needed for the study will be collected.

- When monitoring is complete and both systems have been removed from your baby, the research team will ask you to complete a short, survey to obtain your opinion about the wireless sensors. It should only take 1-2 minutes of your time. This survey will be de-identified with your baby's study identification code to protect you and your baby's privacy. In the event, you are unable to complete the survey upon removal of the monitoring systems, you will able to complete the survey at a time that is convenient for you.

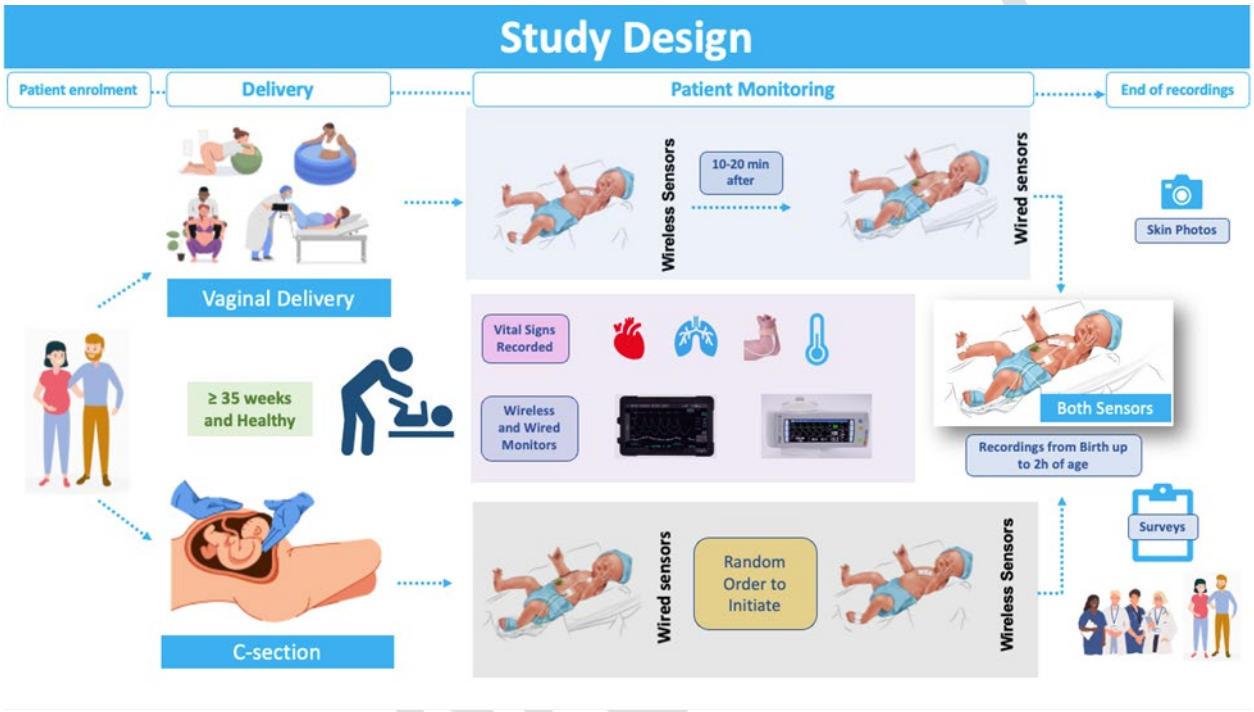

Figure 1. Study design illustration

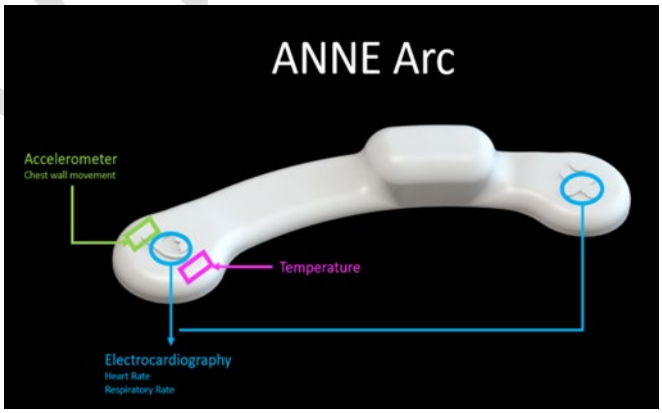

Figure 2. Amplified image of the ANNE Arc sensor. The sensor has 2 ECG leads (HR and RR), a temperature sensor (skin temperature), and an accelerometer (body movements).

Figure 3. Image of Masimo Radical-7 Pulse Oximetry device and root

WHAT ARE THE RISKS?

The risks and discomforts of participating in this study are low because the study relies on data collection, physical examination, and non-invasive devices and techniques. There is a small risk of the adhesive, the sticky material on the pad that attaches the wireless sensor to your baby's skin, irritating your baby's skin and causing mild redness or bruising. While the application of monitoring systems may disturb your baby, every effort will be made to minimize disturbing you or your baby while placing and removing the monitoring systems.

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 25$ amazon gift card as compensation for participating in this study.

SHOULD YOU SUFFER ANY HARM

Should your baby suffer harm of any kind related to this research study, your baby will receive all the care and services required by their state of health.

By agreeing to participate in this study, you are not waiving any of your baby's rights nor discharging the doctors in charge of the study, the sponsor, or the institution of their civil and professional responsibilities.

HOW IS PRIVACY ENSURED

All study data collected during this research study (including personal information and personal health information) will remain confidential to the extent provided by law. You will be identified by a code only. The key to the code linking your name to your study file will be kept by the doctor in charge of this study.

During your participation in this study, the doctor in charge of the study and the research team will collect the information about you and your baby needed to meet the scientific objectives of the study in a study file.

The following information will be collected: basic clinical information from your and your baby's medical chart, images, vital sign recordings, survey responses, and other relevant clinical information for the integrity and purposes of the study.

As part of this study, and potential future research studies to improve the feasibility, accuracy, and safety of vital sign monitoring of babies after birth, you and your baby's de-identified data collected during the study may be shared with academic or commercial third parties and used by the research team in other related research studies. Any use of your or your baby's data in future research studies will be approved by appropriate institutional research ethics boards and no data that could identify you or your baby will be shared. All data will be kept confidential to the extent required by applicable laws. By signing this form, you are consenting and permitting the research study team to share your data with academic and commercial third parties for this study as well as for other future research studies related to improving vital sign monitoring in babies after birth. All required data sharing agreements will be in place prior to releasing your data to any third party.

The study data will be stored for 15 years by the researcher responsible for the study.

For auditing purposes, the research study files which could include documents that may identify you may be examined by a person mandated by the study sponsor, the institution, or the Research Ethics Board. All these individuals and organizations will have access to your personal data, but they adhere to a confidentiality policy.

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

For your safety, a copy of this signed consent form and some information about the research study will be filed in your and your baby's medical record.

IS YOUR PARTICIPATION VOLUNTARY AND CAN YOU WITHDRAW?

Your participation in this study is voluntary. You may choose not to have your baby participate in this study. You may also withdraw your baby from the study at any time, without giving any reason, by informing a member of the study team. Your decision not to participate in the study, or to withdraw from it, will have no impact on the quality of care and services to which you are otherwise entitled, or on your relationship with the teams providing them.

You will be informed in a timely manner if any information becomes available that may impact your willingness to continue participating in this 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.

If you withdraw or are withdrawn from the study, no further data, clinical information, images, or vital sign recordings will be collected. However, the data, clinical information, images, or vital sign recordings already collected for the study will be stored, analyzed, and used to ensure the integrity of the study, as described in this document.

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.

CLINICAL TRIAL REGISTRATION

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, in accordance with American and Canadian law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

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).

If you have any questions concerning your baby's 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 Prospective Multicenter International Study.

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 a decision. After reflection, I consent for my child and I to participate in this research study in accordance with the conditions stated above, including the use of all personal data and information collected.

I authorize the research team to access my and my child's medical chart to collect the information relevant to this project.

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)

_____

Name of parent(s) or legal guardian Signature Date
(Print)

I have explained to the participant and/or his parent/legal guardian 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 (signature) Date
(Print)