Title: Hypotension prediction index to predict epidural-labor analgesia induced hypotension—PILOT

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INFORMED CONSENT STATEMENT AND AUTHORIZATION FOR RESEARCH

Hypotension Prediction Index to Predict Epidural-Labor Analgesia Induced Hypotension

Principal Investigator:
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Funding source: Edwards LifeSciences, Irvine, CA

ABOUT THIS RESEARCH

You are being invited to take part in a research study. We want you to understand the research before deciding to participate. Your participation is voluntary. That means you can choose if you want to take part in this study. You do not need to participate in this study and your participation in this study will not change your quality of care.

This consent and authorization form will summarize important information about this study to help you decide whether you want to participate. Please read this form and ask any questions you have before agreeing to be in this study.

Your doctor may be involved as an investigator in this research study. Before agreeing to participate, or at any time during your study participation, you may discuss your care with another doctor who is not associated with this research study. You are not obligated to be a part of any research study offered by your doctor.

KEY INFORMATION

You are being asked to take part in a research study to investigate the use of a continuous blood pressure monitor to measure blood pressure after epidural-labor analgesia. The study team will explain the study to you and will answer any questions you might have. You should take your time to make your decision.

PURPOSE

The purpose of this study is to compare the time needed to treat changes in blood pressure between a standard blood pressure cuff that is placed on your upper arm and a device, called the *ClearSight Monitor*, you wear on your finger. The ClearSight monitor has been approved by the United States Food and Drug Administration (FDA) for use in intensive care units and after surgery. We intend to determine whether this device is useful for detecting blood pressure changes that are found in approximately 20-30% of patients after receiving an epidural for pain management during labor and

delivery. All patients who receive an epidural for pain management during labor and delivery wear a blood pressure cuff to monitor blood pressure. This study will investigate if the blood pressure monitor you wear on your finger is better than the Conventional Blood Pressure cuff at indicating when patients have low blood pressure after epidural-labor analgesia. All participants will wear the standard blood pressure cuff and the finger blood pressure monitor during this study.

OVERVIEW OF PARTICIPANT ACTIVITIES

If you are eligible and interested in participating in this study, you will have a blood pressure cuff placed on your upper arm and a finger-monitor placed on the same hand. Prior to your decision to get epidural-labor analgesia, we will begin monitoring your blood pressure on both devices to make sure your blood pressure measures are available for the clinical team to monitor. After receiving the epidural-labor analgesia by an anesthesiologist, your blood pressure will be monitored using both devices. You will be randomly assigned to one of two groups: a conventional blood pressure cuff monitoring group or the finger cuff monitoring group.

In the Conventional monitoring group, the nurses and anesthesiologists will see your blood pressure readings from the arm cuff, but not the finger cuff. ***This group is the same as our regular care in the labor and delivery suites.*** In the Finger cuff monitoring group, the nurses and anesthesiologist will see blood pressure readings from the monitor of the finger cuff *in addition to* the conventional arm cuff.

At the end of the 4-hour monitoring period, you will be asked to complete a short survey asking about your experience and acceptability of wearing the finger monitoring cuff.

OVERVIEW OF RISKS

Risks associated with this study include those that are:

- Risks of wearing the finger cuff blood pressure monitor may include:
    - the inconvenience/discomfort associated with the finger monitor.
    - There is an infrequent risk that the device could read your blood pressure as low when it was not. This means you might receive some additional fluids by your IV which otherwise you would not have.
- Less likely: potential breach of confidentiality, meaning someone could see your private information that is not authorized.

Steps have been taken to minimize these risks as much as possible.

OVERVIEW OF BENEFITS

You will receive close monitoring during this study, which may allow for more rapid treatment of hypotension if it occurs. We hope that the information obtained in this research study will help us to develop effective, safer, and faster response to changes in blood pressure after the start of epidural-

labor analgesia. If you decide not to participate in this research, you will receive your normal routine obstetric and delivery care. Whether you decide to participate in this research or not, will have no influence the routine care for you and your baby during and after your delivery. Your participation in this research study is completely voluntary and you may decide to stop participating at any time during the study.

Please review the rest of this document for more details about this study and the things you should know before deciding whether to participate in this study.

WHY IS THIS STUDY BEING DONE?

We are conducting this study to determine whether the finger cuff blood pressure monitor, ClearSight, improves the time it takes to treat hypotensive events after the initiation of epidural-labor analgesia. Hypotensive events, or low blood pressure, are common among patients who receive anesthesia such as an epidural.

WHO IS BEING ASKED TO PARTICIPATE?

We are asking you if you want to be in this study because you:

- Are pregnant and preparing to deliver.
- Are planning a vaginal delivery
- Are planning on receiving epidural labor analgesia (ELA).

HOW MANY PEOPLE WILL TAKE PART?

You will be one of 30 participants taking part in this study.

WHAT WILL HAPPEN DURING THE STUDY?

Prior to receiving your epidural, we will collect some information about your medical history. This information may be collected from you or your medical record. We will monitor your blood pressure prior to the placement of the epidural-labor analgesia as well as for the four hours following the placement of the epidural.

Prior to initiation of epidural labor analgesia, we will collect information such as your baby's gestational age and heart rate measures, your BMI, demographic information from your medical record, and heart rate and blood pressure from hospital monitors. We will also collect additional information from you, the clinical team caring for you, or your medical record. We will also set up both blood pressure monitors and ensure that they are attached and working properly so your care team can see your readings.

After initiation of epidural labor analgesia, we will collect information from your medical charts from your delivery. This information includes your blood pressure, heart rate, and any treatments needed during the epidural anesthetic. We will also collect data about your baby's heart rate. Your care team will monitor your blood pressure every few minutes after you receive your epidural. After delivery, we will gather information about the method of delivery and the health of your baby at birth, such as baby weight, APGAR scores and cord blood pH (we will not collect your baby's blood).

End of procedures. Your participation will end at the time of your delivery.

WHAT ARE THE RISKS OF TAKING PART IN THE STUDY?
You may be uncomfortable wearing both blood pressure monitoring devices for an extended period. You may also be uncomfortable while answering the survey questions. While completing the survey, you can skip any questions that make you uncomfortable or that you do not want to answer. There is an infrequent risk that the device could read your blood pressure as low when it was not. This means you might receive some additional fluids by your IV which otherwise you would not have.

WHO WILL PAY FOR MY TREATMENT IF I AM INJURED?
If you believe that the research procedures have resulted in an injury to you, immediately contact the Principal Investigator who is listed on the first page of this form. Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. Your insurance provider may be billed for the costs of this emergency treatment, but none of those costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care. Currently, there is no financial compensation for participating in this research. You do not waive any rights by signing this form.

WHAT ARE THE BENEFITS OF TAKING PART IN THIS STUDY?
You will receive close monitoring during this study, which may allow for more rapid treatment of hypotension if it occurs. Additionally, we hope to learn things from this study that will help other people in the future and make delivery safer for both laboring mothers and their babies.

WILL I BE PAID FOR PARTICIPATION?

You will be paid up to $25 for participating and completing this study. You will be paid on a reloadable debit card. Your name, address, and social security number are needed to create or load the card and this information will be released to the Accounting Office. All compensation is taxable income to the participant. If you receive $600 or more in a calendar year from one organization, that organization is required by law to file a Form 1099 – Miscellaneous with the IRS and provide a copy to the taxpayer. Individuals who do not provide a social security number may still participate in the research, but the IRS requires that 24% of the payment be sent by the institution to the IRS for 'backup withholding;' thus you would only receive 76% of the expected payment.
Your data and specimens used in this research study may contribute to a new discovery or treatment. In some instances, these discoveries or treatments may be of commercial value and may be sold, patented, or licensed by the investigators and the University of Pittsburgh for use in other research or the development of new products. You will not retain any property rights, nor will you share in any money that the investigators, the University of Pittsburgh, or their agents may realize.

WILL IT COST ME ANYTHING TO PARTICIPATE?
There is no direct cost to you for taking part in this study.

HOW WILL MY and MY INFANT'S INFORMATION BE USED?

The study team is asking your permission to collect medical record information from you and your baby. The information collected may include:

1. Collecting information to make sure you meet the criteria to be in this study.
2. Gathering information about medical history to include in the research data.
3. Checking on your health in the future to help answer our research question, or
4. To inspect and/or copy your research records for quality assurance and data analysis.

The information released and used for this research will include parts of your medical records. Those records may contain information related to your blood pressure, heart rate, and your response and treatment during epidural analgesia. This information will be available for an indefinite period of time and your authorization does not expire.

The following individuals and organizations may access or use your identifiable health information:

- The researchers and research staff conducting the study.
- Representatives of the Office of Research Protection of the University of Pittsburgh for the purpose of monitoring the conduct of the research.
- Regulatory agencies as required by law.
- State or Federal agencies with research oversight responsibilities, including but not limited to:
    - Office for Human Research Protections (OHRP)
    - The FDA (Federal Food and Drug Administration)

A description of this research will be available on ClinicalTrials.gov, as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results from all individuals who participated in the study. You can search this website at any time as it will be updated with the latest results of the study findings.

HOW WILL MY INFORMATION BE PROTECTED?

Every effort will be made to keep your and your infant's personal information confidential, but we cannot guarantee absolute confidentiality. No information which could identify you will be shared in publications about this study.

Researchers may release information about you when you say it is okay. For example, you may still give them permission to release information to insurers, medical providers, or others not connected with the research.

WHO SHOULD I CALL WITH QUESTIONS OR PROBLEMS?

For questions about the study, please contact the study research coordinator during normal business hours, Olivia Jarvis, at 412-641-2179. For emergencies, the PI, be contacted at 412-641-1000.

WHAT IF I DO NOT PARTICIPATE OR CHANGE MY MIND?

After reviewing this form and having your questions answered, you may decide to sign this form and participate in the study, or you may choose not to participate in the study. This decision is up to you. If you choose not to participate in this study or change your mind after signing this document, it will not affect your usual medical care or treatment or relationship with UPMC or the University of Pittsburgh.

If you choose to withdraw your authorization for use and disclosure of your protected health information from your medical record, you must do so in writing by notifying Dr. Lim at:

Dr Grace Lim
Department of Anesthesiology & Perioperative Medicine
300 Halket Street Suite 3510
Pittsburgh, PA 15213

If you withdraw your authorization, you will not be able to continue in this study. However, even if you cancel this authorization, the research team, research sponsor(s), and/or the research organizations may still use information about you that was collected as part of the research project between the date you signed this document and the date you cancelled this authorization. This is to protect the quality of the research results. Otherwise, this authorization remains valid until the research ends and required monitoring of the study has been completed.

Per University of Pittsburgh policy, all research records must be maintained for at least 7 years following final reporting or publication of a project and for children until they reach age of 25.

The researchers may stop your participation in the study even if you do not want to stop if the study doctor determines that it is in your interest.

You will be told about new information that may affect your health, welfare, or willingness to stay in the study.

PARTICIPANT'S CONSENT AND AUTHORIZATION

The above information has been explained to me and all my current questions have been answered. I understand that I am encouraged to ask questions, voice concerns or complaints about any part of this research study during this study. Any future questions, concerns or complaints will be answered by a qualified individual or by the investigator(s) listed on the first page of this consent document at the telephone number(s) given. I understand that I may always request that my questions, concerns, or complaints be addressed by a listed investigator. I understand that I may contact the Human Subjects Protection Advocate of the Human Research Protection office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations that occurred during my participation. By signing this form, I consent to participate in this research study and provide authorization to use and share my medical records and my infant's medical records. A copy of this consent form will be given to me.

_____
Participant's Printed Name **Date & Time**
_____
Participant's Signature

Person obtaining Consent Printed Name **Date & Time**

Person obtaining consent signature.