The Cleveland Clinic Foundation
Consent to Participate in a Research Study

Study title: Postoperative Consequences of Intraoperative NOL Titration
NCT04679818

Sponsor: Medasense, Inc.

Principal Investigator: Kurt Ruetzler, MD 216-636-0561
After hours phone contact #: Kurt Ruetzler, MD 216-407-4108

KEY INFORMATION

The following is a short summary of this research study to help you decide whether or not to be a part of this research study. More detailed information is included later on in this document.

What should I know about a research study?

- Someone will explain this research study to you.
- You can choose whether or not to take part.
- You can agree to take part and then later change your mind.
- Your decision whether or not to participate will not be held against you.
- You can ask all the questions you want before you decide.

What is the purpose, procedures and duration of this study?

We invite you to take part in a research study because you are scheduled for surgery. The purpose of this trial is to determine if the PMD-200, a device designed to guide your anesthesiologist, reduces nociception during recovery.

Nociception:
Anesthetized patients under anesthesia do not perceive pain (or anything else). Nevertheless, painful surgical stimuli initiates a molecular response in nerve and the brain which might be harmful.

The PMD-200 is a noninvasive experimental device that evaluates the amount of surgical pain during general anesthesia. The system is designed for doctors to give the right amount of pain medicine during anesthesia. The device is not approved by the Food and Drug Administration (FDA) but is used in Europe and Canada.

You will be asked to sign informed consent to participate in the study. After you consent to be part of the study, the study team will collect some information about you such as your age, sex, height, weight, and your opioid use over the past month. You will be connected to a PMD-200 monitor. You will be randomized, like flipping a coin, to one of the 2 study groups: either routine anesthetic care or anesthesia guided by the PMD-200 monitor. You will not be told which group you are assigned to. Other aspects of anesthesia and surgery will be per routine. In

all cases, anesthesiologists will do what they believe is best for you. Surgical pain will be treated as necessary during recovery.

Your participation in the research will last until after 60 minutes of recovery after your surgery.

More detailed information can be found under the section labeled: "Information on the Research."

Why might you choose not to participate in this research study?

The PMD-200 is an experimental device. It is a probe that fits on the finger (nothing injected through the skin), and has sensors in it to detect pain impulses in your body. It generates a number which the anesthesiologist can monitor during surgery. It is possible that it will misguide clinicians, and that you will consequently be given too much or too little pain medicine during anesthesia. Neither will increase your chances of having memories of surgery, and pain will be treated as necessary during recovery.

More detailed information about the risks of this study can be found in the section labeled "Risks."

Why might you choose to volunteer for this study?

If the PMD-200 works as expected, you may have less pain than usual in the first hours after surgery. Your participation in this study will help doctors better understand and manage pain from surgery.

More detailed information about the benefits of this study can be found in the section labeled "Benefits."

What are my other choices if I do not take part in this study?

Your alternative is not to participate. If you chose not to, the anesthesia for your surgery will be determined by your anesthesiologists using routine methods.

More detailed information about the alternatives to this study can be found in the section labeled "Alternatives."

DETAILED INFORMATION

The following is more detailed information about this study in addition to the information listed above.

1. INFORMATION ON THE RESEARCH

Why is the research study being done?

The research is being done to test a new type of monitoring during your surgery to see if the management of your pain from your surgery is handled better. The device being used is the MedaSense PMD-200 which is an experimental device which is not yet FDA approved. The device is approved for use in Europe and Canada.

How Many People Will Take Part in this Study?

Approximately 144 people will take part in this study at Cleveland Clinic.

What is involved if you decide to take part in this research study?

You will be asked to sign informed consent to participate in the study. After you consent to be part of the study, the study team will collect some information about you such as your age, sex, height, weight, and your opioid use over the past month. You will be connected to a PMD-200 monitor. You will be randomized, like flipping a coin, to one of the 2 study groups: either routine anesthetic care or anesthesia guided by the PMD-200 monitor. You will not be told which group you are assigned to. Other aspects of anesthesia and surgery will be per routine. In all cases, anesthesiologists will do what they believe is best for you. Surgical pain will be treated as necessary during recovery.

The PMD-200 monitor is attached to the outside of your finger, and has four sensors in it, 1) temperature, 2) photoplethysmography (detects blood pressure changes using light), 3) Galvanic skin response probe (measures things like sweating or electrical changes), and 4) accelerometer (detecting motion). All the probes are attached to a computer, which generates a number designed to give the anesthesiologist an idea how much pain you might be having despite being under general anesthesia.

Your data may be sent outside of the Cleveland Clinic for review by Medasense, Inc who is sponsoring this study. Any personal information that could identify you will be removed before data are shared.

2. ALTERNATIVES

What are the alternatives to participation in the research study?

Your alternative is not to participate. If you chose not to, the anesthesia for your surgery will be determined by your anesthesiologists using routine methods**.**

3. RISKS

What are the risks of participating in the research study?

The PMD-200 is an experimental device. It is possible that it will misguide clinicians, and that you will consequently be given too much or too little pain medicine during anesthesia. Neither will increase your chances of having memories of surgery, and pain will be treated as necessary during recovery.

<u>Confidentiality Risks</u>

There is a potential risk of loss of confidentiality of your data. Efforts will be made to keep your information confidential through the use of the following safeguards: If you decide to be in this study, the study researchers will get information that identifies you and your personal health information. This may include information that might directly identify you, such as your name and address. This information will be kept for the length of the study. After that time it will be destroyed or de-identified, meaning we will replace your identifying information with a code that does not directly identify you. The principal investigator will keep a link that identifies you to your coded information, but this link will be kept secure and available only to the principal investigator or selected members of the research team. Any information that can identify you will remain confidential. Any personal information that could identify you will be removed or changed before files are shared with other researchers or results are made public.

4. BENEFITS

What are possible benefits of participating in the research?

Participation in this study may decrease the amount of pain you experience during recovery from surgery. There is no guarantee that you will personally benefit by participating in this research study. Your participation in this study may provide information that may help other people who have surgery in the future.

5. COSTS

Are there any costs to you if you participate in this study?

There is no cost to you to be in this research study.

6. PAYMENT

Are there any payments to you if you participate in this study?

You will not be paid for taking part in this research

7. RESEARCH RELATED INJURY

What will happen if you are injured as a result of taking part in the research?

In the event you suffer a research related injury as a result of being in this study, Cleveland Clinic will provide appropriate medical treatment for such injury in a timely manner. Provision of such medical treatment does not imply any negligence or other wrongdoing on the part of Cleveland Clinic or any of the physicians or other personnel involved in the study. If you believe that you have been injured as a result of participating in the study, please immediately contact your Cleveland Clinic study doctor even if you may have already been seen or treated by another doctor. If you are seen or treated by a doctor other than the study doctor, you should inform such doctor that you are in this study and, if possible, take this document with you as it may help such doctor treat you.

8. PRIVACY AND CONFIDENTIALITY

What will happen to your information that is collected for this research?

Cleveland Clinic may share your study information, without anyone knowing that it is related to you specifically, with others or use it to research projects not listed in this form. Your data may be stored and shared for future research without additional informed consent if identifiable private information, such as your name and medical record number, are removed. If your identifying information is removed from your data, we will no longer be able to identify and destroy them.

Study results may be shared in medical journals, at scientific meetings, and in other media without your identifying information. Your records will be confidential and your identity will not be shared in medical journals, at scientific meetings, and in other media without your express consent.

Authorization to Use/Disclose Protected Health Information

Cleveland Clinic has rules and procedures to protect information about you. Federal and State laws also protect your privacy.

The research team working on the study will collect information about you. This includes your health information, data collected for this research study and personal identifying information including your name, address, date of birth and other identifying information.

Generally, only people on the research team will know your identity and that you are in the research study. However, sometimes other people at Cleveland Clinic may see or give out your information. These include people who review research studies including the Institutional Review Board and Research Compliance, their staff, lawyers, or other Cleveland Clinic staff.

People outside Cleveland Clinic may see your information for this study. Examples include government groups (such as the Food and Drug Administration), safety monitors, other hospitals in the study and the sponsor of the research and their agents. Cleveland Clinic will take steps to ensure your information is kept confidential and that only the health information which is minimally required to conduct the study is used or disclosed to people outside Cleveland Clinic; however, people outside Cleveland Clinic who receive your information may not be covered by this promise.

You do not have to give this permission to use and give out your information; however you will not be able to participate in this research study without providing this permission by signing this consent form. The use and disclosure of your information has no expiration date.

You may cancel your permission to use and disclose your information at any time by notifying the Principal Investigator in writing, Kurt Ruetzler, MD, Cleveland Clinic Anesthesiology Department of Outcomes Research, 9500 Euclid Avenue, Cleveland, OH 44195. If you do cancel your permission to use and disclose your information, your participation in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in the study.

Clinical Trials Language

A description of this clinical trial will be available on http://www.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. You can search the Website at any time.

9. QUESTIONS

Who do you call if you have any questions or problems?

If you have any questions or concerns about the research, or develop a research-related problem, you should contact Kurt Ruetzler, MD at 216-636-0561. During non-business hours, weekends and holidays, please contact Kurt Ruetzler, MD at 216-407-4108. If you have questions about your rights as a research subject, you should contact the Institutional Review Board at (216) 444-2924.

10. VOLUNTARY PARTICIPATION

What are your rights as a research participant?

Taking part in this study is voluntary. You will be told of any new, relevant information from the research that may affect your health, welfare, or willingness to continue in this study. You may choose not to take part or may leave the study at any time. Withdrawing from the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to withdraw from the study you should discuss with your study doctor your decision to ensure a safe withdrawal.

If you leave the study early, Cleveland Clinic may use or give out your health information that it has already collected if the information is needed for this study or any follow-up activities.

Please notify Dr. Kurt Ruetzler of your decision if you would like to withdraw from the study by calling 216-444-4000 pager 25711.

11. SIGNATURES

Statement of Participant

I have read and have had verbally explained to me the above information and have had all my questions answered to my satisfaction. I understand that my participation is voluntary and that I may stop my participation in the study at any time. Signing this form does not waive any of my legal rights. I understand that a copy of this consent will be provided to me. By signing below, I agree to take part in this research study.

_____

Printed name of Participant

_____ _____

Participant Signature Date

Statement of Person Conducting Informed Consent Discussion

I have discussed the information contained in this document with the participant and it is my opinion that the participant understands the risks, benefits, alternatives and procedures involved with this research study.

_____

Printed name of person obtaining consent

_____ _____

Signature of person obtaining consent Date