STUDY NUMBER: CASE1816

NCT NUMBER: NCT03150758

STUDY TITLE: Intra-operative Assessment of Cavernosal Nerve Stimulus Threshold

PRINCIPAL INVESTIGATOR: Eric Klein, MD

06/01/2018

The Cleveland Clinic Foundation

Consent to Participate in a Research Study

Study title: Intraoperative Cavernous Nerve Neurostimulation in Radical Prostatectomy

Sponsor: None

Primary Investigator: Eric A Klein, MD (216)444-5591

Co-Investigators: Bradley Gill, MD; Yaw Nyame, MD

Contact Information: (216)445-7242 (ask for Dr. Gill or Dr. Nyame) during business hours.

After hours, call (216)444-2200 and ask for the urology resident on-call.

You are being invited to participate in a research study. A research study is designed to answer specific questions about new ways to prevent, detect, and treat disease. Being in a research study is different from being a patient. The purpose of this document is to provide a written summary of the discussion and exchange of research information you had with the research team. It is also for use as a reference during the study.

Please note:

- **You are being asked to participate in a research study**
- **Ask as many questions as needed so you can make an informed decision.**
- **Carefully consider the risks, benefits, and alternatives of the research**

- **Your decision to participate is completely voluntary and will have no effect on the quality of your medical care if you choose not to participate. You can also withdraw from the study at any time.**

1. INFORMATION ON THE RESEARCH

Why is the research study being done?

The purpose of this study is to generate information on the amount of electrical stimulation to the nerves facilitating erection men undergoing radical prostatectomy can receive without developing an erection. This information will be used to help develop therapies to improve erectile and urinary function, which are both commonly affected, after surgery.

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

If you participate in this study, during your prostate surgery a small electric pulse will be applied to the nerves that supply the penis using a sterile electrode. This will be done through the standard surgical incision used to remove your prostate. The pressure within the penis generated by this stimulation will be measured using a small sterile needle inserted into the side of the penis. The goal of this study will be to determine what the lowest amount of electrical stimulation is that a man can receive without developing an erection. There will be no tissue or blood collected from you during your surgery.

2. ALTERNATIVES

What are the alternatives to participation in the research study?

Because our study is a simple test during surgery, the alternative is to not participate and to undergo your surgery without the brief period of electrical stimulation.

3. RISKS

What are the risks of participating in the research study?

There is a theoretical risk of injury to the cavernous nerve, which supplies the penis, as a result of electrical stimulation. If this were to occur, it would further increase the risk of erectile dysfunction after surgery, which ranges from 50% to 80% after surgery without electrical stimulation. The small needle that will be placed into the side of the penis during surgery to measure the pressure presents a negligible risk of bleeding and bruising, infection, or pain at the site of the needle insertion. Such events are rare with needle insertion into the penis and can often be managed easily by a urologist with non-invasive treatments. It is expected the research procedure will add up to 30 minutes to your total operative time.

There are no additional risks of significant bleeding or injury to structures near the prostate. There may be risks or side effects related to the study drug/device that are unknown at this time. You will be notified of any significant new findings that become known that may affect your

willingness to continue in the study. All information collected during this trial will be stored in a secure database on a Cleveland Clinic password protected computer. No identifiable information (i.e., medical record number, date of birth, full name) will be stored in our database. Each patient will be assigned a non-identifiable code that will be used in our database, and the key for the code will be kept in a separate password secure file that can only be accessed by the co-investigators.

Potential risks for injury related to the study are mostly from needle insertion to the penis for pressure recording and consist of: penile bleeding, penile bruising, needle-site infection, and needle-site pain. These issues are mild in severity and are familiar to urologists due to the use of penile injections and penile needle insertion in routine practice. Overall, these events pose a low risk to you and are all easily treatable, usually with no need for an additional intervention. If this type of injury were to occur, you will be able to receive the medical care necessary to address this during and after your hospitalization for prostate surgery.

Nerve damage during surgery occurs as a result of surgical manipulation of the nerves and results in erectile dysfunction. If electrical stimulation were to further injure the nerve this would not be identifiable in the setting of the surgical injury. The risk of electrical stimulation is low. Electrical stimulation has been proven safe for many nerves in the body. Treatment of erectile dysfunction after prostate surgery would be the same whether or not nerve stimulation was studied. You have the option to pursue further treatment if you develop erectile dysfunction from your surgery and participating in the study will not impact your ability to do this if you choose.

4. BENEFITS

What are possible benefits of participating in the research?

This study will likely not provide a direct benefit to you. This study may benefit men who undergo prostatectomy in the future by providing parameters for electrical stimulation that can be used as a treatment to help promote nerve recovery and the return of erectile function after radical prostatectomy.

5. COSTS

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

There are no direct costs to participants in this study

6. COMPENSATION

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

You will not receive any monetary compensation for participating in this study. The research done in this study may lead to the development of new products in the future. You will not receive either now or in the future any compensation, royalty, or other financial benefits resulting from any product, procedure, or other items developed from studying your cavernosal nerves.

7. RESEARCH RELATED INJURY

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

In the event you are injured as a result of participation in this research, medical care is available to you. The costs of such medical care will be billed to you or your insurance company. There are no plans to provide compensation for lost wages, direct or indirect losses. The Cleveland Clinic will not voluntarily provide compensation for research related injury. You are not waiving any legal rights by signing this form. Further information about research related injury is available by contacting the Institutional Review Board at (216) 444-2924.

8. PRIVACY AND CONFIDENTIALITY

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

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 data collected for this research study, your name, and possibly 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 your information.

These include people who review research studies, such as the Institutional Review Board and Research Compliance teams, their staff, lawyers, or other Cleveland Clinic staff.

People outside Cleveland Clinic may need to see your information for this study. Examples include government groups (such as the Food and Drug Administration), safety monitors, and the sponsor of the research or their agents. Cleveland Clinic will do our best 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, **Eric A Klein, MD (9500 Euclid Ave, Mail Stop Q10-1, 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.

9. QUESTIONS

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

Call +1 (216) 444-2200 and ask for Dr. Gill or Dr. Nyame during business hours. After hours, ask for the urology resident on-call.

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.

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