

Cleveland Clinic Florida
Consent to Participate in a Research Study

Study Title: Correlation between Vasopressin and Renal Function Following a Controlled Intraabdominal Pressure Elevation

Sponsor: Cleveland Clinic

Principal Investigator: Raul Rosenthal, MD

Study Coordinator: Mindy Mund, RN

After Hours Phone#: (954) 659-5000 and ask for the surgical 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.**

Your doctor may be an investigator in this research study, and as a research investigator, is interested in both your welfare and in the conduct of the research study. Before entering this study or at any time during this research, you may ask for a second opinion about your care from another doctor who is not involved with the research study. You are not under any obligation to participate in any research project offered by your doctor.

1. INFORMATION ON THE RESEARCH

Why is the research study being done?

The purpose of this study is to evaluate the relationship between the elevated pressure in the chest, belly, and the brain (intracranial) during laparoscopic procedures, and the relationship between the elevated intracranial pressure and hormone release (vasopressin, which may cause your blood pressure to rise), urine output and urine and blood concentration by measuring their values at different time-points. We are interested in learning more about the underlying mechanisms that regulate the functional changes that occur following an increase in belly

pressure. In the last years this topic has become a topic of interest because of the wide spread of laparoscopy.

Why Are You Being Asked To Take Part In This Research?

You are being asked to be part of this study because you have been scheduled for a sleeve gastrectomy surgery.

How Many People Will Take Part In The Study?

An estimated group of 42 patients will be selected to take part in this study

How Long Will You Be In The Study?

You will be in the study during the time of your surgery and one day after.

What Is Involved In The Study?

A Foley (indwelling) catheter is required for this study. Your surgeon may or may not have ordered one based on your medical history. If one was not ordered, it is your choice to have one inserted for the study, or not to have one placed and not participate in this study. Your decision not to participate will not affect your surgery or your care.

If you agree to participate in this study, the following tests and procedures will be performed.

During your surgery at 4 different time points:

1. Measurements of the pressure in your abdomen and chest: These are standard measurements your anesthesiologist will collect during your surgery.
2. Your urine output will be measured by the nursing staff every shift starting at the beginning of your surgery, until post-operative day 1. The catheter will be removed the morning after surgery. Urine will be collected to evaluate the level of hormones in your urine. Urine will be collected for standard of care and research purposes.
3. You will have blood samples collected by venipuncture to measure the level of hormones in your blood. These will be collected for standard of care and research purposes.
4. You will have measurements of your optic (eye) nerves taken with an ultrasound picture. An ultrasound uses sound waves to provide a picture of the eye's internal structure. This will be performed by a fellow on the surgical team and is for research purposes only. The ultrasound of the eye will be done with a probe gliding over the eyelid. It may cause some pressure on your eye but you will not be aware of this because you will be under anesthesia.
5. Measurements from the breathing machine you will be on during the surgery will also be recorded. These are standard measurements collected during surgery.

The day after surgery:

1. You will have an additional blood draw to measure the levels of hormones in your blood. This test is for research only. The blood will be removed through a needle stick in your arm. If possible, this blood will be drawn at the same time as your other blood tests so that you do not have an extra needle stick.
2. If the Foley (indwelling) catheter has been removed, you will be asked to urinate into a container. We will collect a urine sample from the container.

2. ALTERNATIVES

What are the alternatives to participation in the research study?

The alternative is not to participate. You will receive you sleeve gastrectomy surgery as discussed with your doctor.

3. RISKS AND DISCOMFORTS

What Are The Risks Of The Study?

Your doctor will discuss the surgical risks with you that are considered part of the Standard of Care. The following are risks associated with the procedures related to this study. A Foley (indwelling) catheter may be uncomfortable (pain at insertion site or abdominal pressure), may cause infection, or may cause the inability to be able to urinate after it is removed (though less likely if it is in for a short duration of time).

The ultrasound of your eye will be done while you are asleep. You should not feel the pressure of the small probe on your eye lid. There is a small risk of infection from the probe, but it will be sterilized prior to the use of it in surgery.

Blood draws may cause discomfort. There is a possibility that you may develop a bruise at the site. There is also a small risk of infection, or you may feel faint during the blood draw.

There is a small risk to the confidentiality of your data. The safeguards to protect your data are as follows: Data will be stored in a secured folder within the protected Cleveland Clinic Florida network drive, under password encrypted access, limited to the research team, under the principal investigator's supervision and authorization.

4. BENEFITS

Are There Benefits To Taking Part In The Study?

There is no personal benefit to you by participating in this research study. The knowledge to be gained from this research may be beneficial for other patients, society or science.

5. COSTS

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

There will be no additional costs to you for participating in this study. The costs for the urine and blood tests, the eye ultrasounds, and Foley (indwelling) catheter will be paid for by the research study.

6. COMPENSATION

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

You will not be compensated for participating in this research.

7. RESEARCH RELATED INJURIES

What Happens If An Injury Occurs?

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 1 (800) 223-2273 Ext. 42924.

8. PRIVACY AND CONFIDENTIALITY

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 need to 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 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, **rosentr@ccf.org or Raul J Rosenthal, MD 2950 Cleveland Clinic Blvd., Weston, FL 3333**. 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.

“A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.”

9. QUESTIONS

Whom Do You Call With Questions Or Problems?

If you have any questions, concerns or complaints about the research, or develop a research-related problem, contact **Dr Rosenthal (954)659-5239**. After hours you can contact the **surgical resident on call at (954) 659-5000**. If you have questions about your rights as a research subject, you should contact the Institutional Review Board at 1 (800) 223-2273, Ext. 42924.

10. VOLUNTARY PARTICIPATION

What Are Your Rights As A 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. SIGNATURE

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