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The Cleveland Clinic Foundation
Consent to Participate in a Research Study

Study Title: Registry Based, Randomized Controlled Trial Comparing Intra-operative Urinary Catheter vs no Catheter for Laparoscopic Inguinal Hernia Repair

Principal Investigator: Michael J. Rosen, MD (216) 445-3441

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.

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?
You are being asked to participate in a clinical research study because you are scheduled to undergo a laparoscopic repair of your inguinal hernia, as part of your medical care. The purpose of this research is to learn whether inserting a urinary catheter during surgery reduces urinary retention (the inability to urinate) after surgery.

Your participation in the research will last about 30 days after your surgery.

Why might you choose not to participate in this research study?
Currently, some surgeons insert urinary catheters during surgery and some do not. It is not known whether one way is better than another. If you take part in the study, neither you nor your doctor will choose whether you receive a urinary catheter during surgery or not.

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?
We hope the information learned from this study will benefit medical science and provide information which may help improve the field of groin hernia surgery.

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

DETAILED INFORMATION

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

1. INFORMATION ON THE RESEARCH

Why are you being asked to take part in this research?
You are being asked to participate in a clinical research study because you are scheduled to undergo a laparoscopic repair of your inguinal hernia, as part of your medical care.

Why is the research study being done?
When the groin hernia is repaired laparoscopically (small incisions and using a camera and monitors), one of the risks associated with this approach is urinary retention (being unable to urinate) after the procedure. When urinary retention happens, it can be uncomfortable. Urinary retention can be treated by temporarily inserting of a bladder catheter. No clear pre- or intra-operative cause has been associated with the development of urinary retention.
In an attempt to reduce the occurrence of urinary retention, some surgeons insert a urinary catheter at the beginning of the surgery and remove the urinary catheter at the end of surgery.

We are conducting this study to determine whether the use of a urinary catheter during the surgery has any effect on urinary retention after the surgery.

How many people will take part in this study?
We anticipate that approximately 400 patients will be enrolled in this study.

What is involved if you decide to take part in this research study?
If you agree to participate by signing the informed consent, you will have screening assessments completed. At this study visit, the doctor will ask about your past medical and surgical history and any medications you are taking, and you will have a brief physical examination. If you qualify for study participation, your doctor will discuss that with you. If you choose to participate in the study, the study staff will collect additional information such as your gender, age, height, weight, your medical and surgical history, and information relating to your current inguinal hernia. You will be asked to fill out baseline questionnaires that reflect the current pain level related to your inguinal hernia, and your perception of your quality of life at this appointment. The questionnaires will take approximately 5 minutes to complete.

Preoperative Visit
This will be your first meeting with your surgeon. During this visit, your surgeon will evaluate you for an inguinal hernia. If your surgeon believes that you are a candidate for inguinal hernia repair through the laparoscopic approach and that you meet the criteria for this study, he/she will discuss this with you. You will be given this informed consent document, and any questions that

you have related to this study will be answered. Basic information about your health will be collected, and a physical examination will be performed. In addition you will fill a questionnaire relating to your pain and quality of life. These are standard of care procedures for all of our patients regardless of their participation in the study.

Day of Surgery

If you participate in this study, you will be assigned to a study group by chance using a process similar to the coin flip. This process is called randomization. This means that half of the people in this study will receive an intra-operative urinary catheter and half will not receive one. Randomization will occur at the time of the operation after induction of general anesthesia. You will not know if you received a urinary catheter until the end of the study period which will be your 30-day follow up visit.

Your surgery will be performed in the usual manner. As standard of care, your doctor will collect information about your hernia or your surgery, such as the size and type of your groin hernia, how long the surgery took, antibiotics and IV fluids that are given. The use of intra-operative urinary catheter will be collected as well. While this information is standard of care, it will also be used for study purposed.

After your surgery, we will follow standard post-operative care and you will go home once the surgeon deems you fit for discharge. In the event that you develop urinary retention while in the hospital you will be treated according to the protocol of the hospital and/or surgeon who is performing the procedure. The treatment of this complication will be exactly the same as the patients who are not in the study. In the event that you are discharged from the hospital and you develop any of these symptoms: inability to urinate, painful and urgent need to urinate, pain or bloating in the lower abdomen, please seek medical attention immediately. You may call your surgeon during regular business hours. If you are unable to reach your surgeon or if this occurs after hours, please call the clinic operator at (216) 444-2000 or (800) 223-2273 and ask for the General Surgery resident on call. Similarly, if you are having the surgery in Florida please contact your surgeon during regular business hours. After hours, please call the clinic operator at after hours, please call the clinic operator at (954) 659-5000 and ask for the General Surgery resident on call. If you are unable to reach anyone from the hospital please seek medical attention at the nearest emergency department.

Additionally, information regarding your procedure (operative time, intraoperative findings, the size of your hernia, etc.) will be abstracted from your medical records to be included in this study. Your active participation in this study will last for 30 days and it will involve one preoperative evaluation visit, one operative procedure visit, and one post-operative visit. All the other procedures are standard of care and will occur despite your participation in this study.

Follow-Up

You will be given instructions to return to the physician's clinic to be examined your doctor one month (±15 days) following your surgery. This time period for follow-up is standard of care.

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You will have your incisions and wounds evaluated and examined for general health and hernia recurrence. You will be asked about any medications you are taking and about any problems that you might have had with your inguinal hernia repair. Information about any admissions to the hospital or any subsequent procedures that may have been performed during this time will be collected. In addition to standard of care procedures, you will be asked to complete the same surveys that you filled out prior to surgery at each of these visits. At the one month follow-up appointment you will be informed whether an intra-operative urinary catheter was used during the procedure and that will conclude your study participation.

2. ALTERNATIVES

What are the alternatives to participation in the research study?

Your participation in this study is completely voluntary. You do not have to take part in this study if you do not want to participate. Your choice to participate or not will have no impact on the clinical care you will receive from your doctor. Whether or not you receive a urinary catheter during surgery will be based on your surgeon's usual practice. Should you decide to take part and later change your mind, you can do so at any time.

3. RISKS

What are the risks of participating in the research study?

The risks related to the operation are not related to your participation in this study and will be addressed with your doctor during your preoperative clinic evaluation. Dissection and placement of the mesh can be performed safely and efficiently with or without the urinary catheter, and the participating surgeons in this study are considered proficient to perform the operation with or without the urinary catheter.

Urinary Catheter: The following risks have been described and associated with insertion of urinary catheter: development of urinary tract infection, urethral (the tract that leads to the bladder) injury, bladder injury and bleeding with urination.

Urinary Retention: The following risks have been described and associated with urinary retention if left untreated: bladder damage, formation of the pouches in the bladder (called diverticula), hypertrophy of the bladder muscle, congestion of the kidneys, and kidney failure.

Questionnaires: It is possible that some of the questions may be upsetting or you may feel uncomfortable answering them. If you do not wish to answer a question or participate in a portion of the non-invasive testing, we will skip that portion of the study.

Personal Health Information: There is a small risk to the confidentiality of your data. Safeguards are in place to protect your information. Data will be stored on a password-protected computer at Cleveland Clinic that is accessible only to the study staff.

4. BENEFITS

What are possible benefits of participating in the research?

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If you agree to take part in this study, there is NO direct medical benefit to you. We hope the information learned from this study will benefit medical science and provide information which may help improve the field of groin hernia surgery.

5. COSTS

There will be no additional costs to you as a result of taking part in this study. However, routine medical care for your condition (the care you would receive whether or not you were in this study) will be charged to you and/or your insurance company. You will be responsible for any co-payments and deductibles that are standard for your insurance coverage.

6. COMPENSATION

Are there any payments to you if you participate in this study?
There are no payments to you should you decide to participate in this study.

7. RESEARCH RELATED INJURY

What will happen if you are injured as a result of taking part in the research?
In the event that 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 your health information, data collected for this research study, and personal identifying information including your name, address, date of birth, and other identifying information. This information will be used for the stated purpose of the study.

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 included people who review research studies including the Institutional Review Board and Research Compliance, their staff, lawyers, or other Cleveland Clinic staff. If you agree, your personal physician may be informed of your participation in the study.

Your information will be uploaded to a national database: the Americas Hernia Society Quality Collaborative (AHSQC). This is a nationwide registry used to collect information about hernias and hernia operations and has the objective of improve the quality of care provided to hernia patients. This is a secure database and your information will not be shared in any manner that it could identify you, or with purposes not related to quality improvement or research.
People outside of Cleveland Clinic may need to see your information for this study. Examples include government groups (such as the Food and Drug Administration) and safety monitors.

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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 have no expiration date.

You may cancel your permission to use and disclose your information at any time by notifying the Principal Investigator in writing, Michael Rosen MD, 9500 Euclid Avenue, Cleveland, Ohio 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.

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. If the results of this study are published, your identity will remain confidential.

9. CONFLICT OF INTEREST

Do the researchers or institution have any conflicts of interest relating to this study?
Yes, Dr. Rosen is the Founder and Chief Executive Officer of the Americas Hernia Society Quality Collaborative (AHSQC) Foundation. He receives a salary for these services. The AHSQC will receive and store data collected as part of this research project. These financial interests are being managed and are within permissible limits established by the Cleveland Clinic's Conflict of Interest Policy. If you have any questions regarding these conflicts of interests, please ask your doctor or call the Cleveland Clinic Institutional Review Board at (216) 444-2924.

10. QUESTIONS

Who do you call if you have any questions or problems?
If you have any questions, concerns, or complaints about the research or develop a research-related problem, contact Michael J. Rosen, MD at (216) 445-3441 during regular business hours (8am-5pm). After hours, please call the clinic operator at (216) 444-2000 or (800) 223-2273 and ask for the General Surgery resident on call. If you are having the surgery in Florida please contact Dr. Emanuele Lo Menzo at 954-659-5249 during regular business hours (8am-5pm). After hours, please call the clinic operator at (954) 659-5000 and ask for the General Surgery resident on call. If you have questions about your rights as a research subject, you may contact the local Cleveland Clinic Institutional Review Board at (216) 444-2924.

11. 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

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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.

You may refuse to be in or remove yourself from the study at any time without providing a reason, and this will not affect the standard of care you receive. To withdraw from the study, tell the principal investigator you no longer want to participate by contacting Michael Rosen, MD at 216-445-3441. If you are having the surgery in Florida please contact Dr. Emanuele Lo Menzo at 954-659-5249

If you choose to withdraw from the study, you will be followed based on the standard of care at your institution. The investigator can remove you from the study without your approval. Possible reasons could be if participation appears to be medically harmful to you, if it is discovered that you do not meet eligibility requirements, or if the study is canceled.

12. 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 signed 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 in this research study.

_____
Printed Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent Date