THE UNIVERSITY OF TENNESSEE HEALTH SCIENCE CENTER

Main Consent Form

TITLE: Post-operative bladder filling after outpatient laparoscopic hysterectomy and time to discharge: a randomized controlled trial

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1. KEY INFORMATION:

A person who takes part in a research study is called a research or study subject. In this consent form "you" refers to the research subject and/or the legally authorized representative.

You are being given the opportunity to participate in this research study. The purpose of this consent form is to help you decide if you want to be in the research study.

During surgery, a catheter is placed in your bladder and then removed in the operating room once the surgery is complete. In order to be discharged home, all outpatient surgical patients need to void (empty the bladder) spontaneously. We are studying whether filling the bladder with sterile normal saline in the operating room instead of leaving it empty allows patients to void sooner and go home faster.

Some of the most common side effects from having a catheter include bladder irritation or discomfort and less commonly a urinary tract infection. Some patients have difficulty urinating after surgery and rarely need a catheter to be replaced. These risks are for all patients undergoing laparoscopic hysterectomy as a catheter is required for surgery.

The purpose of this study is to assess whether filling your bladder postoperatively will reduce the time to void and subsequent discharge to home after a laparoscopic hysterectomy.

Subject Initials _____

Procedures:
In this study, we will randomize subjects between different postoperative bladder catheter plans to compare the time to urinate and be discharged home.

You will be randomly assigned (like the flip of a coin) to have sterile fluid placed in your bladder before the removal of your catheter (group A) or not (group B). You have a 1 in 2 chance of having fluid placed in your bladder, the experimental treatment. The investigator will not be the person who decides which you receive. A computer program that gives random numbers will be used to decide which you receive. You will not be told whether or not fluid was placed in your bladder.

Your participation in this study will last up to one month. You will have the usual post-operative office visits after your surgery.

The following procedures are being performed for research purposes only:
- Copying information such as your medical history, etc. from your medical record
- Randomization to either group A (have sterile fluid placed in bladder) or Group B
- If you are randomized to group A, instillation of 200mL of sterile normal saline post-operatively
- Collecting data about your postoperative course

For a detailed explanation of the procedures, refer to the section of this consent form entitled, DETAILED PROCEDURES TO BE FOLLLOWED.

Risks:
If you are placed in the group that will have fluid placed in the bladder, there is a risk of the bladder becoming too full. Because of this concern, we will only fill the bladder about half-way.

If you are placed in the group that will not have fluid placed in the bladder, it may take longer before you can void and be ready for discharge from the Surgery Center.

For a detailed list of the potential risks, refer to the section of this consent form entitled, RISKS ASSOCIATED WITH PARTICIPATION.

Benefits:
Your time to discharge home after surgery may improve while you are in this study; however, this cannot be promised. The results of this study may help people undergoing laparoscopic hysterectomy in the future by being able to urinate and go home quicker.

Subject Initials _____

Alternatives:
You may undergo a laparoscopic hysterectomy without participating in this study. You do not need to be in this study to receive treatment for your condition.

Voluntary Participation:
Your participation in this research study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled.
Deciding to not take part in this research study will not change your regular medical care in any way.

If you are a student of the University of Tennessee, participating or not participating in this study will in no way influence your grade in any course. If you are a resident or fellow of the University of Tennessee, participating or not participating in this study will in no way influence your academic standing. If you are an employee of University of Tennessee participating or not participating in this study will not affect your employment status.

2. DETAILED PROCEDURES TO BE FOLLOWED:

One hundred and twelve (112) subjects will be participating in this study.

The study will take place at:	
University of Tennessee Health Science Center Obstetrics and Gynecology First Floor Rout Building 853 Jefferson Avenue, E102 & E149 Memphis, TN 38103	Administrative Data collection, transmission & storage.
Regional One Health – Outpatient Center Obstetrics and Gynecology Clinic 880 Madison Avenue, 3rd Floor Memphis, TN 38103	Clinical visits- examination, evaluation, consenting: creation of medical record information.
Regional One Health Chandler Bldg. - Surgery Center 877 Jefferson Avenue Memphis, TN 38103	Surgical Procedure and creation of medical record information

Visit 1 (Day 0)

- Give informed consent at your routine doctor visit (this will take an additional 30-45 min)– for research purposes only;

Subject Initials _____

- Information such as your age, weight, height, and medical history such as [previous heart attacks, etc.] will be copied from your medical record. Specifically, the following items will be collected: age, race, ethnicity, insurance status (public vs. private), body mass index (BMI), medical comorbidities, surgical history, preoperative medications, history of bladder problems, history of neurologic problems, history of chronic pain, and tobacco use; (this will take an additional 30-45min)– for standard of care and for research purposes;

Visit 2 (Day 1)

- Post-anesthesia randomization to group A or group B, (this will take an additional 5-10min)– for research purposes only;
- Post-operative instillation of sterile saline into bladder (group A only), catheter removal (group A & B); (this will take an additional 30min-1 hour)– for research purposes only;
- If you are unable urinate on your own, a catheter will be placed in the bladder to collect your urine and you will monitored in the hospital until the catheter is removed and you are able to urinate spontaneously; (this procedure will take an additional 30-45min)– for standard of care;
- Post-operatively, the following kinds of information will be collected from your medical record: indication for the procedure, intraoperative urinary tract injury, surgical complications, estimated blood loss, intra-operative and post-operative IV fluids, intra-operative narcotic administration, time of first post-operative voiding (group A & B); urine output, time to hospital discharge – for research purposes only; *this does not require any additional time for you*;

Visit 3 **(**Day 14 to Day 30)

- In person, in the clinical office, follow-up assessment; (this will take an additional 15-30min)– for standard of care and for research purposes;
- Post-operatively, the following kinds of information will be collected from your medical record: pathology reports, need for post-operative catheterization, post-operative opioid use, post-operative urinary tract infection– for research purposes only; *this does not require any additional time for you*;

Adverse events will be monitored and collected through the Day 30 visit, to include the following categories: death, life-threatening, hospitalization (initial or prolonged), disability or permanent damage, required intervention to prevent permanent impairment or damage (devices), other serious (important medical events). This will be accomplished through assessment of all body systems, with specific focus on: bladder irritation or discomfort.

Your participation in this research study may be stopped by the study doctor without your consent for any of the following reasons:

- If you do not show up for visits

Subject Initials _____

- If you do not follow the study doctor's instructions

If you decide to stop being part of the study, you should tell your study doctor, and any information that you have already provided will be kept in a confidential manner.

3. RISKS ASSOCIATED WITH PARTICIPATION:

All patients undergoing laparoscopic hysterectomy have a bladder catheter placed at the time of the procedure as a standard of care, so the risks associated with the placement of a bladder catheter do not differ for patients who are or are not part of the study.

If you are placed in the group that will have fluid placed in the bladder, there is a risk of the bladder becoming too full. Because of this concern, we will only fill the bladder about half-way.

If you are placed in the group that will not have fluid placed in the bladder, it may take longer before you can void and be ready for discharge from the Surgery Center.

There is a risk that your private identifiable information may be seen by people not involved in the research (such as if a researcher's computer is stolen or an electronic database is hacked). However, we will use very careful security measures (such as locks on file cabinets, computer passwords, etc.) to minimize the chance that any unauthorized persons might see your confidential information.

The research may involve risks to you which are currently unforeseeable. You will be told about any new information that might change your decision to be in this study. You may be asked to sign a new consent form if this occurs.

4. CONFIDENTIALITY:

Research records
All your electronic research records will be computer password protected and accessible only to research personnel and those entities named below in this section, except as required by law (such as reports of child abuse, plans to commit suicide, etc.).

A master key/list which links your name with the code on your research record will be maintained at:

University of Tennessee Health Science Center
Obstetrics and Gynecology
First Floor Rout Building,
853 Jefferson Avenue, E149
Memphis, TN 38103

Subject Initials _____

Your private information collected as part of this research, even if identifiers are removed, will not be used or distributed for future research studies.

Medical Records
Information about your participation in this study or the results of procedures performed in this study will be placed in your medical record. As such, it may be available to your insurer. However, it will not be available to your employer, except with your explicit authorization and/or as permitted by law.

Presentations/Publications
While individual details about your case might be provided in publications or presentations about this research, they will not be discussed in a way that would allow you to be individually identified as a participant.

Limits to Confidentiality
Information obtained during the course of the study, which in the opinion of the investigator(s) suggests that you may be at significant risk of harm to yourself or others, may be reported to a third party to protect the rights and welfare of those at potential risk.

Authorization to Use and Disclose Protected Health Information for Research Purposes
Under federal privacy regulations, you have the right to decide who can review and copy your identifiable health information (called "protected health information" or PHI). PHI collected in this study may include information such as:

- Past and present medical records
- Records about your study visits
- Records about phone calls made as part of this research
- Research records

By signing this consent form, you are giving your permission for the study doctor and the study staff to get your PHI from your doctor and/or facilities where you have received health care. They may also share your PHI with:

- The Institutional Review Board (IRB) at the University of Tennessee Health Science Center
- Regional One Health

Your PHI will only be used and/or given to others:

- To do the research
- To study the results
- To see if the research was done correctly

Your PHI will be used until the study is completed.

Subject Initials _____

You may withdraw or take away your permission to use and disclose your PHI at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you may not be able to stay in the study.

When you withdraw your permission, no new PHI will be gathered after that date. However, information that has already been gathered may still be used and given to others. The federal regulations allow you to review or copy your PHI that is used in this study.

However, in order to complete the research, your access to this PHI may be temporarily suspended while the research is in progress. Once the study is over, your right to review and copy your PHI will be reinstated.

5. COMPENSATION AND TREATMENT FOR INJURY:

You are not waiving any legal rights or releasing the University of Tennessee, Regional One Health**,** or the agents of either, from liability for negligence. In the event of physical injury resulting from research procedures, the University of Tennessee and Regional One Health do not have funds budgeted for compensation for medical treatment. Therefore, the University of Tennessee and Regional One Health do not provide for treatment or reimbursement for such injuries.

If you are injured or get sick as a result of being in this study, call the study doctor immediately. The study doctor will provide acute medical treatment and will provide you with a subsequent referral to appropriate health care facilities.

If you are injured or get sick as a result of being in this study, you and/or your insurance will be billed for the costs associated with this medical treatment.

No compensation will be available to you for any extra expenses that you may have as the result of research-related physical injuries, such as additional hospital bills, lost wages, travel expenses, etc.

No compensation will be available to you for any non-physical injuries that you may have as a result of research participation, such as legal problems, problems with your finances or job, or damage to your reputation.

6. QUESTIONS:

Contact John Schorge, MD at 901-448-2531 if you have questions about your participation in this study, or if you have questions, concerns, or complaints about the research.

If you feel you have had a research-related injury, contact John Schorge, MD at 901-545-7345. This is a 24-hour/7-day telephone number located in the Labor and Delivery area of Regional One Health Hospital.

You may contact Cameron Barclay, MSA, UTHSC IRB Director, at 901-448-4824, or visit the IRB website at http://www.uthsc.edu/research/compliance/irb/ if you have any questions about your rights as a research subject, or if you have questions, concerns, or complaints about the research.

7. PAYMENT FOR PARTICIPATION:

You will not be paid for participation in this research study.

Successful research using information about your health and your specimen (even if identifiers are removed) could result in commercial products, such as a drug to treat your disease. You will not share in any financial rewards associated with the development of these products.

8. COSTS OF PARTICIPATION:

There are no additional costs to you for participating in this study.

9. FUTURE CONTACT:

If we lose contact with you during the study for any reason (your phone number changes; your physical or email address changes; you are not responding to our attempts to contact you about your continued participation; etc.), we will attempt to find you or make contact with you in the following ways:

- The phone number(s) you provided to us will be called, but if you are not the person who answers, we will not say the title of the study or the fact that you are/were participating in a study.
- A letter will be sent to the address(es) you provided to us, but neither the return address nor any markings on the envelope will identify the title of the study or the fact that you are/were participating in a study.

Put your initials on one of the lines below:

_____We CAN attempt to find/contact you in the above ways.

_____We MAY NOT attempt to find/contact you in the above ways.

Subject Initials _____

10. CONSENT OF SUBJECT:

You have read or have had read to you a description of the research study as outlined above. The investigator or his/her representative has explained the study to you and has answered all the questions you have at this time. You knowingly and freely choose to participate in the study. A copy of this consent form will be given to you for your records.

_____ _____ _____
Signature of Research Subject (18 years +) **Date** **Time**

_____
Printed Name of Adult Research Subject

_____ _____ _____
Signature of Person Obtaining Consent **Date** **Time**

_____
Printed Name of Person Obtaining Consent

In my judgment, the subject or the legally authorized representative has voluntarily and knowingly given informed consent and possesses the legal capacity to give informed consent to participate in this research study.

_____ _____ _____
Signature of Investigator **Date** **Time**