THE UNIVERSITY OF TENNESSEE HEALTH SCIENCE CENTER

Main Consent Form

TITLE: Pain with differing insufflation pressures during laparoscopic hysterectomy

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1. KEY INFORMATION:

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.

Insufflation is the process of blowing a gas, routinely carbon dioxide, into the abdominal cavity to allow for visualization of the internal structures by the surgeon during a laparoscopic procedure. Insufflation of the abdominal cavity results in shifting the abdominal wall outwards and the diaphragm, a dome shaped muscle below the lungs, upwards. This results in an increase in intra-abdominal pressure (IAP) and a reduction of chest volume. Post laparoscopic referred shoulder pain is thought to arise from irritation in the abdominal cavity.

The purpose of this study is to determine the effect of decreased insufflation pressure on postoperative pain, pain medication need/use, and surgical safety and feasibility for laparoscopic hysterectomy.

Procedures:
In this study, we will be collecting data from your medical record as you complete visits for your clinical care. We will also be asking you to complete some additional questionnaires about your level of pain post-operatively.

You will be randomly assigned (like the flip of a coin) to undergo laparoscopic hysterectomy with peritoneal insufflation pressure set to 15 mm Hg (standard-group A) or 12 mm Hg (comparison group B). You have a 1 in 2 chance of receiving insufflation pressure of 12 mm Hg

pressure, the comparison 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. It is not known whether peritoneal insufflation pressure set to 15 mm Hg (standard-group A) is as good as, better than, or worse than peritoneal insufflation pressure set to 12 mm Hg (comparison group B).

You will not know which insufflation pressure group you are assigned. The surgeon will find out once you are under anesthesia. This is important for the research design so that as few people as possible will know about the developing trends in the research information being gathered.

There is a possibility of increased operative time associated with the 12 mmHg (group B) versus the 15 mmHg (group A). However, if the surgeon determines that increased insufflation pressure is needed to complete the surgery, the pressure will be adjusted and this information will be recorded.

All participants will be asked to rate their pain with a visual analog scale (VAS) at the following times: pre-operative (up to 2 hours before surgery); post-operative-immediate (the highest level of post-operative pain in the post-anesthesia care unit [PACU] will be recorded); 24 hour post-operative (approximately 24 hours after surgery), and 2 weeks after surgery (at the follow-up clinic/office visit).

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 standard group A (15 mm Hg) or comparison group B (12 mm Hg)
- Four pain level assessment questionnaires (Visual Analog Scale-VAS)
- Collecting data about your post-operative course

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

Risks:

Risks for patients undergoing a laparoscopic hysterectomy with an insufflation procedure, whether using 15 mm Hg (standard-group A) or 12 mm Hg (comparison group B), include: increased carbon dioxide in the blood, decreased oxygen in the blood, decreased lung expansion, and the collection of air underneath the skin layers. The collection of gas can cause discomfort and bloating, but it usually dissipates on its own within a few days as your body absorbs it.

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

Benefits:
The results of this study may help people undergoing gynecologic laparoscopic surgery in the future by improving postoperative pain and analgesic requirements.

Alternatives:
You will receive medical treatment for (gynecologic laparoscopy) whether or not you participate in the study.

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 (100) 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, analysis & 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;
- 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), additional medical health conditions, surgical history-prior abdominal surgery, history of chronic pain, history of prior chronic opioid use, pre-operative medications - opioid/analgesic, history of alcohol and tobacco use, history of depression/anxiety; (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;
- Intra-operative insufflation using 15 mm Hg (standard-group A) or 12 mm Hg (comparison group B), adjustment of intra-operative insufflation pressure ; (this will take an additional 5 min-10 min)– if a subject is randomized to the 12 mm Hg group the physician may make the determination that 15 mm Hg is appropriate; insufflation adjustments for group A or group B are done as standard of care;
- Post-operative assessments to include the procedure details: indication for procedure, length, estimated blood loss, surgical complications, estimated blood loss, pathology, visual analog scale (VAS), pain medication-prescribed and taken, length of hospital stay, (this will take an additional 30-45min)– for standard of care and for research purposes;

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

- In person post-operative follow-up assessment; (this will take an additional 15-30min)– for standard of care and for research purposes;
- Collection of post operative pathology reports, post-operative opioid use; (this will take an additional 30-45min)– for standard of care and for research purposes;

Adverse Events Monitoring (Day 1 to Day 30)

- 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: respiratory: decreased respirations, shallow breathing, decreased SPO2; integumentary: swelling, pressure, or crackling sound skin on palpation of skin, increased abdominal distension; neurological: uncontrolled pain.

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
- 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:

Risks for patients undergoing a laparoscopic hysterectomy with an insufflation procedure, whether using 15 mm Hg (standard-group A) or 12 mm Hg (comparison group B), include: increased carbon dioxide in the blood, decreased oxygen in the blood, decreased lung expansion, and the collection of air underneath the skin layers. Additionally, a potential risk/discomfort associated with insufflation referred shoulder pain. The collection of gas can cause discomfort and bloating, but it usually dissipates on its own within a few days as your body absorbs it.

When using 12 mm Hg (the comparison amount) for insufflation, the abdomen may not expand as much as with 15 mm Hg (the standard amount) and possibly lead to decreased visualization of your abdominal organs. As a result this may cause increased operative time, increased blood loss and increased hospital length of stay.

The peritoneum is a thin membrane that covers your abdominal organs and cavity, protecting them from friction and infection. Due to the stretching effect of abdominal insufflation on this membrane, the nerve that carries signals between your brain, heart and digestive system – the vagal nerve – is effected, and can lead to slowed heart rhythms. The chances of this occurring ranges from a commonly occurring, or about once in every 3 surgeries, to rarely occurring, or about once in every 30 surgeries.

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 paper research records will be stored in locked file cabinets and will be 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.).

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

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.

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:

The process of insufflation of carbon dioxide gas to inflate your abdomen for visualization during laparoscopic surgery is the standard of care. If adjustment of insufflation pressure is appropriate during the procedure, the adjustment will increase the operative time. This may or may not impact the cost of your surgery.

You or your insurance carrier will be responsible for costs associated with this standard of care surgical procedure.

You or your insurance company may be billed for:
· Outpatient surgery costs, anesthesia, laboratory tests, prescriptions

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 <u>one</u> 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.

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 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**