INFORMED CONSENT FORM

Title: A Pilot Study: A Comparison of Liposomal Bupivacaine ("Exparel™") to Bupivacaine HCl in Tranversus Abdominis Planus ("TAP") Block for Abdominal Gynecologic Surgery

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The following persons are sub-investigators for this research study:
Jacqueline Kohl, MD
Mitchell Edelson, MD
Elizabeth Burton, MD
Joel Sorosky, MD

You have been asked to participate in a pilot research study. This form is designed to give you information about this research study. The principal investigator or person authorized to obtain your consent will describe the study to you and answer any of your questions. If you have any questions about this research study, you should contact Dr. Heidi Ching at 215-481-4211. If you have an injury related to this research study you should contact Dr. Heidi Ching at 215-481-4211 and the Director of Risk Management at Abington Hospital Jefferson Health at 215-481-2209. If you have any questions about your rights as a human research subject please contact the Director of Risk Management at Abington Hospital Jefferson Health at 215-481-2209. If you have any concerns or complaints about this study, you may contact the Department of Patient Advocacy at Abington Hospital Jefferson Health at 215-481-2499.

Purpose of this research study

Your participation in the study includes consent for the administration of a transversus abdominis plane block ("TAP block"). This procedure is intended to augment the effects of other medications to significantly reduce the intensity of postoperative pain you will experience. An anesthesiologist who is participating in this study will describe the TAP block to you during your preoperative interview, and he or she will obtain your consent for the procedure along with your consent for the anesthesia you will receive for your intended surgery. As part of the study, you will be asked to answer various questions after your surgery regarding your experience of postoperative pain. The total number of research subjects in this study is expected to be approximately 128.

The use of TAP blocks has become regarded as a significant advance in the control of postoperative pain following abdominal surgery. Traditionally TAP blocks are done with use of bupivacaine HCl. Recently a new version of this medication has been approved for injection into surgical site for longer duration pain relief. The purpose of the current study is to evaluate the use of a conventional local anesthetic agent (bupivacaine HCl) compared to the use of a novel form of the same agent (liposomal bupivacaine) which is reputed to have a longer duration of action. Given that this comparison has never been studied before, this study will be a pilot study. The study will help determine whether liposomal bupivacaine has specific

advantages over conventional bupivacaine HCl when given in a TAP block for lower abdominal surgery. The study will measure outcomes such as length of stay in hospital, use of post operative opioids, and monitor for any adverse effects of both bupivacaine HCl and liposomal bupivacaine.

The FDA has approved the use and infiltration of liposomal bupivacaine into the TAP for use of TAP block, and falls within the scope of liposomal bupivicaine's current indications.

All patients undergoing open abdominal surgery performed by Dr, Shahin, Dr. Burton, Dr. Edelson, Dr. Sorosky, or Dr. Kohl will be consented for TAP block by an anesthesiologist. You will be randomly assigned to receive either bupivicaine or the test material (liposomal bupivicaine) through a computer process which is blinded to the surgeon. All TAP blocks will be placed after the abdominal incision is closed but before you are allowed to awaken. Your anesthesiologist will place this TAP block under ultrasound guidance. The anesthesiologist will identify the correct site of infiltration using an ultrasound and test this area with normal saline first. They will then infiltrate the site with either the control (bupivacaine HCl) or the test material (liposomal bupivacaine). You will also receive a narcotic through your IV post operatively before you wake from anesthesia and prior to extubation, no matter which arm of the study you belong to.

Inclusion and Exclusion Criteria

The following patients will be included in our study:

1. TAP blocks placed as the laparotomy incision is closed, but before the patient is awake, to be placed under ultrasound guidance with correct identification of the correct abdominal plane.
2. Consent for TAP block signed by patients preoperatively by anesthesiology

The following patients will be excluded from our study:

1. All pregnant patients
2. All patients under 18 years of age
3. minimally invasive surgery such as laparoscopy or robotic assisted laparoscopy
4. medical contraindications to use of bupivacaine HCl or liposomal bupivacaine

Risks

The most common adverse reactions include itching, constipation, nausea and vomiting (incidence greater than or equal to 10%). Other common adverse reactions include pyrexia, dizziness, anemia, hypothension, prurities (incidence between 2% and 10%). The rare adverse reactions (incidence less than 2%) include, but are not limited to, chills, erythema, bradycardia, pain, edema, syncope. You also may experience typical postoperative pain that may require additional pain medications.

Your participation may be terminated by the investigators if there is clear advantage to using the experimental liposomal bupivacaine over conventional bupivacaine HCl during the duration of the study. Other circumstances under which your participation may be terminated include adverse effect from the local anesthetic you receive. There will be no consequences if you decide to withdraw from the study. Significant new findings that develop during the course of the research, which may affect your willingness to participate, will be provided to you.

Potential health benefits to the subject may include decreased postoperative pain, reduced necessity for narcotic use, and decreased length of stay in the hospital.

There will be no materials such as tissue or blood sent or stored for this study.

Compensation and costs

The research study will have no cost to you specifically. There will also be no compensation to the investigators or the participants for this study.

There will be no waiver of subject's legal rights or release of investigator, sponsor, or institution from negligence

During this study, records that identify you will be kept strictly confidential and will comply with the Healthcare Information Portability and Accountability Act ("HIPAA") throughout the entire process.

In the event of any physical injury resulting from the research procedures, medical treatment will be provided, and you or your third party insurance will be billed. You will be responsible for any copays or deductibles.

If you suffer a physical injury or illness that is deemed to be unrelated to the research procedure, medical treatment will be provided to you. Your third party insurance will be billed for medical expenses associated with treatment provided.

If you have any questions concerning this issue, you may contact a financial counselor to assist you with this process through Abington Hospital Jefferson Health Patient Service Center at 215-481-5777.

By signing this document, you indicate your agreement that all of your questions have been answered and this informed consent has been explained to you in a language understandable to you.

You understand that your participation is voluntary. Refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and you may stop participating in this study at any time without penalty or loss of benefits, to which you are entitled. You will contact Dr. Heidi Ching for procedures to follow prior to ending your participation.

You will receive a copy of this informed consent form.

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.

Print subject name

Subject signature | Date

Print authorized representative name | Date

(or authorized representative name) | Date

Print Witness name | Date

Witness Signature | Date

Print name of person obtaining consent | Date

Authorized person obtaining consent signature | Date

The following persons are authorized to obtain my consent:

Dr. Heidi Ching, Dr. Jacqueline Kohl, Dr. Mark Shahin, Dr. Mitchell Edelson, Dr. Elizabeth Burton, Dr. Joel Sorosky