Title of research study: Transversus abdominus plane (TAP) block catheters vs liposomal bupivacaine for pain control after colorectal surgery: A prospective randomized control trial

Investigator: Jon Zhou, MD

Why am I being invited to take part in a research study?

We invite you to take part in a research study because you are scheduled to receive peripheral nerve blocks for pain control after your elective colorectal surgery.

What should I know about a research study?

- Someone will explain this research study to you, including:
  - The nature and purpose of the research study.
  - The procedures to be followed.
  - Any drug or device to be used.
  - Any common or important discomforts and risks.
  - Any benefits you might expect.
  - Other procedures, drugs, or devices that might be helpful, and their risks and benefits compared to this study.
  - Medical treatment, if any, that is available for complications
- Whether or not you take part is up to you.
- You can choose without force, fraud, deceit, duress, coercion, or undue influence.
- You can choose not to take part.
- You can agree to take part now and later change your mind.
- Whatever you decide it will not be held against you.
- You can ask all the questions you want before you decide.
- If you agree to take part, you will be given a signed and dated copy of this document**.**

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, you can contact the research team during business hours:

Maria Tran, Department of Anesthesiology 916-734-5171

Anesthesia Acute Pain 24 hour Pager: 916-816-6915

To use the 24 hour pager, dial the pager number above. After the tone, enter the phone number where you can be called, press the # key and hang up. A doctor from the Anesthesia Acute Pain team will call you back on the phone number that you provided.

For non-emergency issues you can call the UCDMC Hospital Operator (916-734-2011), tell the Operator you are participating in a research study and you wish to talk to Anesthesiologist on call. In the case of an emergency, dial 911 from any phone.

This research has been reviewed and approved by an Institutional Review Board (“IRB”). Information to help you understand research is on-line at http://www.research.ucdavis.edu/policiescompliance/irb-

admin/.You may talk to a IRB staff member at (916) 703-9151, hs-irbadmin@ucdavis.edu, or 2921 Stockton Blvd, Suite 1400, Room 1429, Sacramento, CA 95817 for any of the following:

- Your questions, concerns, or complaints are not being answered by the research team.
  - You cannot reach the research team.
  - You want to talk to someone besides the research team.
  - You have questions about your rights as a research subject.
  - You want to get information or provide input about this research.

Why is this research being done?

Pain control after laparoscopic surgery of the abdomen is complex and has different components. Opioids, which are drugs similar to morphine, have long been used to treat pain postoperatively. Although they are effective, they have risks and side effects that can lengthen hospital stay including nausea, itching, constipation, and breathing problems. Other ways of treating postoperative pain include medications such as acetaminophen (Tylenol) and non-steroidal anti-inflammatory drugs, and performing peripheral nerve blocks.

Peripheral nerve blocks have long been used to decrease post-operative pain. In abdominal surgery, a widely used nerve block is the transverse abdominus plane block (TAP). At UC Davis, it is standard practice for adult colorectal surgery patients to receive TAP blocks with catheters using a local anesthetic called ropivacaine to improve pain control and decrease the need for opioids. These catheters are usually removed after two days. The alternative single injection TAP block can also be performed using a different local anesthetic called liposomal bupivacaine (Exparel). The purpose of this study is to compare the effectiveness and cost of the two TAP block approaches when used for post-operative pain control in colorectal surgery.

We think patients receiving either one of the TAP block approaches will have satisfactory pain control and that side effects of both approaches will be similar. However, we think that the single injection TAP block approach with liposomal bupivacaine may be more effective (as measured by less need for morphine-like medication) in controlling pain compared to TAP block with a catheter approach. Finally, we also think medical utilization cost may be lower with the single injection approach. The results of this study could improve the care for colorectal surgery patients at UC Davis and possibly other institutions.

How long will the research last?

We expect that you will be in this research study starting from 2 hours prior to your surgery (TAP block will be placed in the preoperative holding area) until the day of your discharge from the hospital.

How many people will be studied?

We expect about 100 people will be in this research study at UC Davis Medical Center.

What happens if I say yes, I want to be in this research?

All patients in this study will receive a TAP block procedure with the use of an ultrasound. You will receive either a single injection TAP block or TAP block with catheters. The treatment you get will be chosen by chance, like flipping a coin. Neither you nor the study doctor will choose what treatment you get. You will have a 50:50 chance of being given each treatment. Both treatment procedures will be

performed in the preoperative holding area by the acute pain service team consisting of an Anesthesiology faculty member and resident. Both procedures are performed before you are put under general anesthesia and before your surgery starts.

Group 1 is the single injection TAP block using liposomal bupivacaine (Exparel). An injection containing the same amount of medication will be administered on each side of the abdomen. Group 2 will receive a single injection on both sides of the abdomen using a different local anesthetic, ropivacaine. This group of patients will also receive peripheral nerve catheters on both sides of the abdomen, which will continue to deliver a set amount of ropivacaine after the surgery using CADD pumps.

Immediately after your surgery, you will be monitored in the Post Anesthesia Care Unit (PACU) where you will receive medications to treat pain (opioids), nausea, and other conditions if needed. You will then be discharged from the PACU and transferred to the inpatient unit where you will continue to receive routine pain medications. Patients enrolled in Group 1 will be seen by our team for next two days to assess pain control. Patients enrolled in Group 2 will be monitored daily by our team until the catheter is removed, which is usually done when patients are able to tolerate oral intake and there is no concern for bowel obstruction. Both groups will be discharged from the hospital after meeting standard criteria.

Throughout your hospitalization, certain information will be collected by our team: ultrasound images from your TAP block, anesthesia record during your surgery, amount of opioids required at different stages of your hospital stay, incidence of side effects such as nausea/vomiting, your reported pain scores, and total time spent in the PACU and inpatient unit.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible to report pain scores and medication side effects such as nausea, itching, constipation to your assigned nurse during the duration of your hospital stay. This is a normal part of your hospitalization even if you do not participate in this research study.

What happens if I do not want to be in this research?

You may decide not to take part in the research and it will not be held against you. If you choose not to participate in this study, you will still be offered a TAP block catheter for pain control, and your surgery will go on as planned.

Instead of being in this research study, your choices may include:

- Receiving a TAP block but your information will not be used in the study
- Declining a TAP block and using another method to treat pain from surgery such as acetaminophen, anti-inflammatory medications, opiates, and other supplemental treatments. Of note, these medications are routine part of your care regardless of your participation in the study.

What happens if I say yes, but I change my mind later?

You can leave the research at any time and it will not be held against you.

Is there any way being in this study could be bad for me?

Although TAP blocks are a minimally invasive procedure, possible risks include bleeding/blood clots, infection, incorrect placement of needles/catheters, and allergic reaction/toxicity from local anesthetics

(liposomal bupivacaine and ropivacaine). The procedure will be performed under strict sterile technique to reduce the risk of infections. The use of an ultrasound machine also decreases the risk of bleeding and incorrect placement of needles and catheters. Allergic reactions/toxicity from local anesthetics are extremely rare, and symptoms can range from itching, swelling, difficulty breathing, abnormal heartbeat, and in extreme cases, death. Even when performed correctly, there is also a risk that the TAP block may not provide adequate pain control after your surgery.

You will be assigned to a study group at random (by chance). Your assignment is based on chance (like a coin flip) rather than a medical decision made by the researchers. The study group you are assigned to might not be the group you would prefer to be in. It might also prove to be less effective or have more side effects than the other study group, or standard treatments available for your condition.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include better pain control and minimization of opiate use during your hospitalization, which can lead to faster recovery.

What happens to the information collected for the research?

Efforts will be made to limit use or disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete confidentiality. Organizations that may inspect and copy your information include the IRB and other University of California representatives responsible for the management or oversight of this study.

The sponsor, monitors, auditors, the IRB, the Food and Drug Administration will be granted direct access to your research records to conduct and oversee the study. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

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 we access protected health information (e.g., your medical record), you will be asked to sign a separate form to give your permission.

Federal law provides additional protections of your medical records and related health information. These are described in the UC Davis Health System Notice of Privacy Practices (http://www.ucdmc.ucdavis.edu/compliance/pdf/notice.pdf) and in an attached document.

Can I be removed from the research without my OK?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include:

- If there was difficulty visualizing anatomical structures using the ultrasound machine which increases the chance of an unsuccessful TAP block.
- If an adverse event occurs after the TAP block procedure and the use of local anesthetics.

We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

What else do I need to know?

There is no charge for you to participate in this study. You or your health plan will be billed for the costs of routine medical care you receive during the study which include TAP block placements. These costs may include operating room fees, pharmacy charges, treatments, hospitalization, scans, etc. You will be expected to pay for the usual deductibles and co-payments, and for any routine care that is not covered.

For more information about possible costs, please contact the research team. The research team can follow UC Davis Uninsured Non-Emergency Estimate Policy (Policy ID 1883) to work with their department and Decision Support Services to get you a cost estimate.

It is important that you promptly tell the person in charge of the research if you believe that you have been injured because of taking part in this study. If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. Depending on the circumstances, the costs of the treatment may be covered by University or the study sponsor or may be billed to your insurance company just like other medical costs. The University and the study sponsor do not normally provide any other form of compensation for injury. For more information about compensation, you may call the IRB Administration at (916) 703-9151 or email at HS-IRBAdmin@ucdavis.edu.

You will not be compensated for taking part in this study.

Permission to Take Part in a Human Research Study

Signature Block for Capable Adult

Your signature documents your permission to take part in this research.

Signature of subject	Date
Printed name of subject	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	

My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject.

Signature of witness to consent process	Date
Printed name of person witnessing consent process	