Comparison of Preoperative Ultrasound Guided Nerve Blocks to Intraoperative Nerve Block Catheters for Breast Reconstruction: A Prospective Randomized Trial

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Title of research study: Comparison of Preoperative Ultrasound Guided Nerve Blocks to Intraoperative Nerve Block Catheters for Breast Reconstruction: A Prospective Randomized Trial

Investigator: Michael S. Wong, 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 undergoing single-stage breast reconstruction. Literature has shown that patients undergoing this procedure may benefit from regional anesthesia with pectoralis nerve blocks. However, it is unknown what environment (pre-operative placement or intraoperative placement of block) leads to the best block outcome, and the use of long term pain catheters for this indication has not been studied.

What should I know about a research study?

(Experimental Subject's Bill of Rights)

- 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.
  - 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, talk to the research team at:

Cannery Building
3301 C St., Suite Suite 1100
Sacramento, CA 95816
Phone: 916-734-7844

For non-emergency issues you can call the UCDMC Hospital Operator (916-734-2011) 24-hours a day, tell the Operator you are participating in a research study and you wish to talk to the Plastic Surgery Resident 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?

Peripheral nerve blocks decrease post-operative pain and therefore narcotic use. While their benefits are clear, little is known about the optimal way to place these blocks – whether it should be done in the operating room, or in the pre-operative area with ultrasound. We are doing this study to examine whether the method of block placement and pain medicine infusion through On-Q catheters impacts efficacy of the block, efficiency of surgery, and patient satisfaction. We hope that this research will lead to improved nerve blocks and increased patient satisfaction with their operative experience.

How long will the research last?

Your participation in this research study will include the day of your surgery and a few hours of your time one week after your surgery, to fill out a short online survey.

How many people will be studied?

We expect about 252 people here will be in this research study

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

If you consent to be enrolled in this research trial, you may be placed into one of **two (2) research groups. The two groups are: Pectoralis nerve block placed by anesthesia before surgery and pectoralis nerve block catheter placement intra-operatively by the surgical team.** Based on where you are in the randomization process, you will be randomized to one or the other treatment arm. 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 be told your treatment group after you sign consent.

- ❑ You will be randomized into one of the two groups
- ❑ You will receive a treatment pre-designated by the randomization process

If you are randomized to receive a pre-operative block group This block will be placed before surgery but after you are under general anesthesia by the anesthesia team, using ultrasound guidance. For the block, an anesthesiologist inject an anesthetic (numbing) medication in the vicinity of the sensory nerves that provide sensation to parts of your chest. The rest of your care will be entirely routine. You will have a normal amount of pain medication after surgery available to you to take as you need.

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Protocol	Approved
918749	June 25, 2018

If you are randomized to the catheter group: During your surgery, your surgeon will place a catheter underneath your pectoralis muscle, near the tissue expander. Pain medicine will infuse slowly over the first four days after your surgery in the vicinity of the sensory nerves that provide sensation to parts of your chest. These catheters will be removed at your first post-operative appointment. The rest of your care will be entirely routine. You will have a normal amount of pain medication after surgery available to you to take as you need.

For all groups, you will complete a short survey that will be emailed to you now and at hours 6 after your surgery. This survey will be emailed to you again at hours 12, 27 and at post-operative day 1-7. An additional 10 question satisfaction survey will be emailed to you one week after surgery. This survey will ask you about the success of your nerve block (if you had one) and your satisfaction with your pain management experience.

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. You may be offered a pre-operatively placed nerve block outside of the study, but this will be up to your anesthesiologist. You can refuse a nerve block without penalty.

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. If you leave after your nerve block has been placed, information about your postoperative course will not be collected.

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

While nerve blocks are generally very well tolerated, there are significant risks that you should be made aware of, including: bleeding including hematoma or hemorrhage, infection and/or abscess, persistent injection site pain, no pain relief or worsened overall pain, temporary or permanent muscle weakness, temporary or permanent nerve damage, temporary or permanent paralysis, seizure, increase or decrease in blood pressure, abnormal heart rhythm, nausea, vomiting, chest pain, allergic or anaphylactic reaction, other less common temporary or permanent medication side effects, retained broken needle fragment. If ULTRASOUND is used: heating and burning of superficial and deep tissue.

With respect to the nerve catheters, potential risks to patients with placement are the same as with the ultrasound guided block but are even less likely, as these catheters are placed under direct visualization. However, the risk of a post-operative infection may be very slightly increased.

Will being in this study help me in any way?

This study may benefit you in that if you receive a nerve block, you may have less post-operative pain and nausea.

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.

During your participation in this research, data will be collected about you. The de-identified data will become the property of the University of California. Because we access protected health information (e.g., your medical record), you will be asked to sign a separate form to give your permission. Your medical records may become part of the research record. 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?

If you are randomized to receive the intra-operatively placed nerve block but do not undergo surgery, you will be withdrawn from the study.

What else do I need to know?

You or your health plan will be billed for the costs of routine medical care you receive during the study. 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. You will not be compensated for taking part in this study.

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 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 IRBAdmin@ucdmc.ucdavis.edu.

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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	

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