[Year]

NCT ID # 03700970

Title: Comparing Local Anesthetics for Transversus Abdominis Plane (TAP) Block During Abdominally-based Free Flap for Breast Reconstruction

10/01/2018

Institutional Review Board
Informed Consent Document for Research

Principal Investigator: XXXXXX MD **Revision Date: October 1, 2018**
Study Title: Comparing local anesthetics for transversus abdominis plane block during abdominally-based free flap for breast reconstruction
Institution/Hospital: Vanderbilt University Medical Center

This informed consent applies to **Adults**

Name of participant:_____Age: _____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study. Your medical record will contain a note saying you are in a research study. Anyone you authorize to receive your medical record will also get this note.

1. What is the purpose of this study?

You are being asked to take part in this research study because you are having surgery to rebuild your breast(s). As part of your pain control plan, you will receive an injection of a drug into the muscles and tissues of the abdomen. This will reduce pain and swelling. This is called a TAP (transversus abdominis plane) block. The purpose of this study is to compare two different drugs used to control pain to see if one is better than the other. The drugs used in this study are: liposomal bupivacaine and plain bupivacaine.

These drugs are approved by the Food and Drug Administration (FDA). About 60 people will take part in this study at VUMC.

2. What will happen and how long will you be in the study?

If you want to take part in this study you will sign this consent form. Your medical records will be reviewed to make sure you are able to take part in this study. You will complete questionnaires which will take about 15 minutes. You will be randomized (like the flip of a coin) to receive liposomal bupivacaine with plain bupivacaine or plain bupivacaine alone. You will not know which drug you are getting.

On the day of your surgery: A TAP block will be done after you receive general anesthesia in the operating room. This means you will not be aware when this procedure is done. The anesthesiologist will use ultrasound to help guide a needle into a space in your abdominal muscles on each side. After the needle is inserted, liposomal bupivacaine with plain bupivacaine or plain bupivacaine alone will be injected in the space. After the medication is injected, the needle will be removed.

You will be given pain medicine as needed during and after surgery as part of your regular care. You will be asked questions about your pain every day while you are in the hospital and on post-op Day 7.

Follow-up: The study team will contact you about 4 times during your recovery period to ask questions about how you are recovering: Day 0-7; Day 7, Day 14 and Day 30. Each time point will take about 10 minutes. These will be completed in clinic or by phone call.

Your participation in this study will last about 30 days.

3. Costs to you if you take part in this study:

If you agree to take part in this research study, you and/or your insurance will not have to pay for the tests and treatments that are being done only for research.

However, you are still responsible for paying for the usual care you would normally receive for the treatment of your illness. This includes treatments and tests you would need even if you were not in this study. These costs will be billed to you and/or your insurance.

You have the right to ask what it may cost you to take part in this study. If you would like assistance, financial counseling is available through the Vanderbilt Financial Assistance Program. The study staff can help you contact this program. You have the right to contact your insurance company to discuss the costs of your routine care (non-research) further before choosing to be in the study. You may choose not to be in this study if your insurance does not pay for your routine care (non-research) costs and your doctor will discuss other treatment plans with you.

4. Side effects and risks that you can expect if you take part in this study:

Liposomal bupivacaine and/or plain bupivacaine

Common

- nausea, vomiting;
- chills or shivering;
- headache; or
- back pain.

Uncommon

- feeling anxious, restless, confused, or like you might pass out;
- problems with speech or vision;
- ringing in the ears, metallic taste, numbness or tingling around your mouth, or tremors;
- seizure (convulsions);
- weak or shallow breathing;
- fast heart rate, gasping, feeling unusually hot;
- slow heart rate, weak pulse;
- urinating less than usual or not at all.

Rare

- allergic reaction

Risks of a TAP block may include:

- infection at the insertion site (where the needle enters your body)
- temporary numbness
- reaction to the anesthesia
- anesthesia injected into a blood vessel instead of the muscle

5. Payment in case you are injured because of this research study:

If it is determined by Vanderbilt and the Investigator that an injury occurred as a direct result of the tests or treatments that are done for research, then you and/or your insurance will not have to pay for the cost of immediate medical care provided **at Vanderbilt** to treat the injury.

There are no plans for Vanderbilt to pay for any injury caused by the usual care you would normally receive for treating your illness or the costs of any additional care. There are no plans for Vanderbilt to give you money for the injury.

6. Good effects that might result from this study:

a) The benefits to science and humankind that might result from this study. Data gathered in this study will provide information about pain control and recovery using these two study drugs.

b) The benefits you might get from being in this study. You may or may not benefit from taking part in this study.

7. Other treatments you could get if you decide not to be in this study:

You do not have to take part in this study.

8. Payments for your time spent taking part in this study or expenses:

You will not be paid to take part in this study.

9. Reasons why the study doctor may take you out of this study:

- The study doctor may take you out of this study if they feel that it is not good for you to continue.
- You withdraw consent.
- The study stops.

If you are taken out of the study you will be told the reason.

10. What will happen if you decide to stop being in this study?

If you decide to stop being part of the study, you should tell your study doctor. Deciding to not be part of the study will not change your regular medical care in any way.

11. Who to call for any questions or in case you are injured:

If you should have any questions about this research study**, Please contact study PI**

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please call the Vanderbilt University Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

12. Clinical Trials Registry.

A description of this clinical trial will be available on 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.

13. Confidentiality:

Your study records will be stored within Vanderbilt University Medical Center: either in locked areas with limited access or within electronic data bases with access limited to the study team only.

Vanderbilt may share your information, without identifiers, to others or use it for other research projects not listed in this form. Vanderbilt, Dr. Perdikis and his staff will comply with any and all laws regarding the privacy of such information. There are no plans to pay you for the use or transfer of this de-identified information.

14. Authorization to Use/Disclose Protected Health Information

All efforts, within reason, will be made to keep your protected health information (PHI) private. PHI is your health information that is, or has been gathered or kept by Vanderbilt as a result of your healthcare. This includes data gathered for research studies that can be traced back to you. Using or sharing ("disclosure") such data must follow federal privacy rules. By signing the consent for this study, you are agreeing ("authorization") to the uses and likely sharing of your PHI. If you decide to be in this research study, you are also agreeing to let the study team use and share your PHI as described below.

As part of the study, Vanderbilt University Medical Center may share the results of your study and/or non-study linked parts of your medical record, to the groups named below. These groups may include people from the Federal Government Office for Human Research Protections, the VUMC Institutional Review Board, Vanderbilt University, the Food and Drug

Administration (FDA), the Vanderbilt Anesthesiology Research Executive Committee (AREC) and insurance companies for billing purposes. Federal privacy rules may not apply to these groups; they have their own rules and codes to assure that all efforts, within reason, will be made to keep your PHI private. The study results will be kept in your research record for at least six years after the study is finished. At that time, the research data that has not been put in your medical record will be kept for an unknown length of time. Any research data that has been put into your medical record will be kept for an unknown length of time.

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Unless told otherwise, your consent to use or share your PHI does not expire. If you change your mind, we ask that you contact Dr. Perdikis in writing and let him know that you withdraw your consent. His mailing address is D4207 MCN, Nashville, TN 37232-2345. At that time, we will stop getting any more data about you. But, the health data we stored before you withdrew your consent may still be used for reporting and research quality.

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

Date	Signature of patient/volunteer

Consent obtained by:

Date	Signature
	Printed Name and Title