TAP Block Study

NCT05537883

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Single Blinded Randomized Trial of Transversus Abdominis Plane Block Using Liposomal Bupivacaine in Metabolic and Bariatric Surgery Patients

Informed Consent Form to Participate in Research

Selwan Barbat MD, Principal Investigator

SUMMARY

You are invited to participate in a research study. The purpose of this study is to determine if laparoscopic TAP block using bupivacaine is equivalent to liposomal bupivacaine in terms of: amount of opioids (narcotic pain medications) needed, postoperative nausea and vomiting, and patient satisfaction. You are invited to be in this study because you have decided to undergo bariatric (weight loss) surgery. It is our standard practice to give local numbing medicine at the time of your surgery as a laparoscopic Transversus Abdominus Plane (TAP) Block. Some surgeons currently use a medication called liposomal bupivacaine and others use plain bupivacaine. We know both medications work well to control postoperative pain, but this is the first study to compare them against each other in patients undergoing bariatric surgery.

Participation in this study will involve completing daily surveys sent to you via the Seamless MD app on your smartphone. We will also collect data from your medical records pertaining to the surgery. This will last approximately 30 days from your surgery. All research studies involve some risks. A risk to this study that you should be aware of is some risk of loss of confidentiality. We will do all we can to keep your information confidential. It is possible some of the items in the survey may make you feel uncomfortable. You may ask to stop participating in the study at any time. It is our standard practice to perform laparoscopic TAP block at the time of surgery and theoretical risks include bleeding and local anesthetic toxicity. Both of these risks are extremely rare and equivalent whether liposomal or plain bupivacaine is used. You may or may not benefit from participation in this study.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. There may be other choices available to you. Some other choices may include undergoing your surgeon's preference of TAP block anesthetic (the usual practice).You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study please contact the Principal Investigator Dr. Selwan Barbat:

[redacted]

[redacted]

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [redacted] or the Wake Forest University Health Sciences Research Subject Advocate at [redacted].

INTRODUCTION

You are invited to be in a research study. Research studies help scientist learn new information that may help other people in the future. You are being asked to be in this study because you have decided to undergo bariatric (weight loss) surgery. Your participation is voluntary. You do not have to be a part of this study if you do not want to. Please take your time in making your decision if you would like to join. Ask your study doctor or the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to compare the effects (good and bad) of plain Bupivacaine with Liposomal Bupivacaine, which are both used to provide pain relief during and after surgery, to see which is better.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

212 patients at one research site (Atrium Health) will be involved in this study.
You are not allowed to take part in this study if you:

- Do not have a smartphone or tablet in which the Seamless MD app can be downloaded
- Cannot speak English
- Are undergoing revisional bariatric surgery or
- Need another procedure at the time of your bariatric surgery (e.g. hiatal hernia repair or ventral hernia repair)
- Take opioid pain medication at home

WHAT IS INVOLVED IN THE STUDY?

You will be randomized into one of the study groups described below. Randomization means that you are put into a group by chance. It is like flipping a coin. You will not know which drug you are receiving. This is done so that a fair evaluation of the results can be made.

If you decide to participate in this study you will be expected to:

- Undergo your weight loss surgery as scheduled. Then,
- Complete daily surveys sent to you via Seamless MD for 2 weeks postoperatively
- Attend your follow-up appointments

HOW LONG WILL I BE IN THE STUDY?

You will be in the study for about 30 days after your surgery. You can stop participating at any time. If you decide to stop participating in the study, we encourage you to talk to the investigators or study staff first. There will be no serious consequences of sudden withdrawal from the study. You should feel not feel pressured to be a part of this study. If you decide not to be in the study, this will not harm your relations with your doctors or with Atrium Health. You are free to stop being in the study if you change your mind after entering it. This would not harm your relations with your doctors or Atrium Health.
The researchers may choose to remove you from the study if there is a medical condition, event, or situation that makes taking part in this study not in your best interest.

WHAT ARE THE RISKS OF THE STUDY?

Being in this study involves some risk to you. You should discuss the risk of being in this study with the study staff. Risks and side effects related to the TAP block drugs we are studying include: bleeding, local anesthetic toxicity. These are very rare.
Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.
There also may be other risks that we cannot predict. You should tell the research staff about all the medications, vitamins, and supplements you take and any medical conditions you have. This may help avoid side effects, interactions, and other risks to your health.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

You are not expected to receive any direct benefit from taking part in this research study. We hope the information learned from this study will benefit other people in the future. There is a potential you may have less postoperative pain in the Liposomal Bupivacaine group.

WHAT OTHER CHOICES ARE THERE?

You do not have to be in this study. You should talk to the researchers about all the choices you have. Instead of being in this study, you have the option of undergoing your surgery with TAP block as usually provided, at your surgeon's recommendation. You could be treated with Bupivacaine or Liposomal Bupivacaine even if you do not take part in the study.

WHAT ARE THE COSTS?

All study costs, including any study products or procedures related directly to the study, will be paid for by the study. Costs for your regular medical care, which are not related to this study, will be your own responsibility. You will not pay extra money to take part in this study.

WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required or permitted by law, or necessary to protect the safety of yourself or others.

Your information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

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.

WILL YOU BE PAID FOR PARTICIPATING?

You will receive no payment or other compensation for taking part in this study.

WHO IS SPONSORING THIS STUDY?

This study is not being sponsored or funded by any company or institution.

WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any information we collect from you or any information we get from your medical records about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes: data pertaining to your surgery, your

use of postoperative narcotic pain medication, your experiences with postoperative nausea or vomiting, and patient satisfaction.

If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study will be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist with the health care operations of Atrium Health, Wake Forest University Health Sciences, and their respective affiliated entities.

We will take steps to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer.

Your personal health information and information that identifies you ("your health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your health information are the study investigators; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and Atrium Health Facilities; representatives from government agencies such as the Food and Drug Administration (FDA) or the Office of Human Research Protections (OHRP), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs, videotapes, audiotapes or other recorded media which are identify you unless we you're your written authorization.

You can tell Dr. Selwan Barbat that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

[redacted]

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form you give us permission to use your Protected Health Information for this study.

If you choose to participate in this study, your medical record at Atrium Health, Wake Forest University Health Sciences, or their respective affiliated entities will indicate that you are enrolled in a clinical trial. Information about the research and any medications or devices you are being given as a participant may also be included in your medical record. Authorization to access this part of the medical record will only be available to people who have a need to know this information in order to perform their job-related duties. If you are not a patient of these health care facilities, a medical record will be created for you anyway to provide access to this important information to providers in case of an emergency.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this Web site at any time.

Laboratory test results and other clinically relevant medical reports created as a result of your participation in the research study may be entered into the computer systems of Atrium Health, Wake Forest University Health Sciences, and/or their respective affiliated entities. These results and reports will be kept secure in compliance with applicable laws, with permission to access this information limited to individuals with proper authority, but who may not be directly involved with this research study.

A medical record will be created for all study participants seen on-site and if a medical record doesn't already exist. Information about your participation in the study will be placed in the medical record, along with any routine medical test results that were obtained as part of this study.

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because of a a medical condition, event, or situation that makes taking part in this study not in your best interest. Information that identifies you may be removed from the data or specimens that are collected as part of this study and could be used for future research or shared with others without additional consent.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or in the event of a research-related injury, contact the study investigator, Dr. Selwan Barbat:

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB at [redacted] or the Research Subject Advocate at [redacted].

You will be given a copy of this signed consent form.

SIGNATURES

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this

consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed):_____

Subject Signature: _____ Date: _____Time:_____ am pm

Person Obtaining Consent (Printed):_____

Person Obtaining Consent:_____ Date:_____ Time:_____ am pm