Official Title:Pecto-intercostal Fascial Block With Perineural Adjuvants for Postoperative Analgesia Following Sternotomy in Patients Undergoing Cardiac Surgery
NCT05676814
IRB-Approved Date: 3/23/2023

Atrium Health
Wake Forest Baptist

Department of Anesthesiology-Section on Regional Anesthesiology and Acute Pain Medicine

PECTO-INTERCOSTAL FASCIAL BLOCK (PIFB) WITH PERINEURAL ADJUVANTS FOR POSTOPERATIVE ANALGESIA FOLLOWING STERNOTOMY IN PATIENTS UNDERGOING CARDIAC SURGERY

Informed Consent Form to Participate in Research
Rawad Hamzi, MD, MS: Principal Investigator

SUMMARY

You are invited to participate in a research study. The purpose of this research is to compare postoperative pain relief provided by the Pecto-Intercostal Fascial Block (also known as PIFB) when the numbing medications are combined with additional medications than when the block is done without the adjuvants. This nerve block has been shown to reduce some of the pain in your chest that you will have after the surgery, and we are interested in finding out if we can reduce the pain more and for longer. You are invited to be in this study because your surgery involves a sternotomy procedure (or an open chest) and you are anticipated to experience pain after your surgery. Your participation in this research will involve answering questions about your pain at 6 hour intervals after your surgery for up to 24 hours. Your total participation in this study will last until 24 hours after your surgery. In addition to receiving the nerve block while still asleep, you will receive the normal types and doses of pain medications you need after your surgery that you would receive if you were not in the study. The nerve block we are studying will be done in addition to the other routine postoperative care you would receive, not instead of it, if you agree to participate.

Participation in this study will involve being randomized (like the flip of a coin) to receive the PIFB block with or without adding the additional medications. You will have an equal chance of being randomly assigned to either group. All research studies involve some risks. One risk of this study that you should be aware of is the small risk of infection at the needle insertion site where the nerve block is performed. This is quite rare, as we do our best to prevent it by performing the block under sterile conditions in the operating room, with sterile gloves, needle, and ultrasound probe cover, and only after scrubbing your skin with cleaning solution. Another risk to be aware of is the small risk of damage to surrounding structures, present with any nerve block or procedure. In the case of PIFB, this could include the inner lining of the chest wall called the pleura, or small blood vessels inside the chest called the internal thoracic vessels. We minimize this risk by using an ultrasound, which allows us to guide the needle throughout the entire block procedure. Both of these risks are much lower than 0.5%. A final risk to know about is toxicity

from receiving too much numbing medicine, or having it go into the blood, called local anesthetic systemic toxicity (LAST). We take this risk very seriously as well, and avoid it by using doses of numbing medicine well within the safe margin for you and your body weight, and frequent, vigilant monitoring that the medicine never goes directly into the blood. This risk would be even rarer than 1 in 2000.

You may experience decreased pain as a result of your participation in this study because this nerve block is not normally performed on this surgery population at our hospital yet. However, many hospitals throughout the country have started doing them after they have been repeatedly shown to be safe and helpful for reducing pain after heart surgery such as yours.

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 to not receive the PIFB and receive only the usual IV and oral pain medications and other analgesics as you would normally receive. 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 at [redacted] (research nurse).

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 are going to have surgery that involves having a sternotomy, meaning an incision through your breast bone, and you are expected to experience pain after your 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 pain relief provided by the Pecto-Intercostal Fascial Block (also known as PIFB) when the local anesthetic numbing medications are

combined with additional medications than when the block is done without the adjuvants.

All of the drugs that are being administered for the PIFB have been approved by the US Food and Drug Administration (FDA) as safe medications. We have been safely using the additional medications for many years in our nerve blocks without issue, but the additional medications have not been formally approved for use in nerve blocks for research purposes. However, these drugs are commonly used in common clinical practice at our facility and others as part of our postoperative pain regimen in the various blocks that are done, and studies have been done showing they are safe to use around nerves. The FDA has reviewed our use of these additional medications in our nerve blocks and has determined them to be safe to the point where we have been granted an exemption from requiring FDA approval.

All the PIFB blocks in this study will be done using local anesthetic medications. There is no placebo involved in the conduct of this research study. A placebo is a substance that is not thought to have any effect on your disease or condition. This means that no matter which group you are in, you will receive a nerve block that should help reduce the pain in your chest after the surgery.

How Many People Will Take Part in the Study?

Twenty people at Atrium Health Wake Forest Baptist will take part in this study. In order to identify the 20 subjects needed, we may need to consent as many as 30 people, because some people will not qualify to be included in the study. For example, if the right side of your heart seems to be requiring extra support with medications or devices at the end of your surgery, we will need to exclude you from inclusion, because this means you likely will need extra time to recover and not be awake as soon after surgery for us to ask you questions about your pain.

What Is Involved in the Study?

You will be randomized into one of the two study groups described below. Randomization means that you are put into a group by chance; it is like flipping a coin, and you will have a 50% chance of being in either group. Neither you, the surgeon, nor the study staff assessing you after your surgery will know which group you are in or the medication mix you will receive in the nerve block. Only the doctor performing the nerve block will know which group you are randomized to so they can mix the medications for it. This “blinding” is done to make sure a fair evaluation of results can be made. If you or the researchers collecting data know which group you were in, this has been shown to bias the results, making the study unreliable. Information about which group you are in is available to the researchers if needed in an emergency.

The 2 groups you may potentially be randomized to differ by the medications used in them. In Group 1 the medications include the use of bupivacaine and epinephrine. Group 2 medications include using bupivacaine, epinephrine, dexamethasone and clonidine. We do not know if the

addition of dexamethasone and clonidine enhance the length of time you receive pain relief from this nerve block. This study hope to determine the best combination to use.

You will be approached during one of the following times: during your pre-anesthesia clinic visit before surgery, in your current hospital room if you are in the hospital awaiting surgery, or on the phone if research staff missed seeing you during your pre-anesthesia visit. At those times, the study will be discussed with you in its entirety. If you are seen prior to the day of surgery, written informed consent will be obtained. If you are approached over the phone, then the consent will be emailed to you at the address you provide for review prior to the day of surgery. Then, on the morning of surgery, you will be seen in the holding room to obtain written informed consent where you sign the consent form.

On the day of surgery, you will be seen by research staff in the holding room to review the study and to get some baseline information. You will be asked to breathe in through an incentive spirometer (a device that measures three times to measure how deeply you are able to inhale). This will be compared to after your surgery. You will also be asked to report a baseline pain score by rating your current pain level on a scale of 0 to 10, with 0 being no pain and 10 being the worst pain imaginable. You will then be randomized into the study.

You will undergo your surgery as planned by you and your cardiac surgeon. At the end of your surgery, after making sure you are still a good candidate, the anesthesiologist will be performing the study PIFB. Your surgeon, other research staff, and the ones caring for you in the intensive care unit will not know which medications you received. At 6, 12, 18, and 24, hours after the nerve block was placed, you will be asked to provide a pain score on a scale of 0-10, with 0 being no pain and 10 being the worst pain imaginable, both at rest and with deep inhale using the incentive spirometer. After your surgery, you will receive the normal postoperative care that you would receive if you were not in the study. That includes receiving IV and oral narcotics to treat your pain, as well as non-narcotics, such as acetaminophen and ibuprofen. After the visit at 24 hours, your participation in this study ends.

How Long Will I Be in the Study?

You will be in the study for about 24 hours 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.

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 PIFB postoperative block we are studying include:

Risks of medications used in nerve block	Nerve blocks are overall very safe. The risks of this type of nerve block are as follows: infection at the injection site, bleeding (rare), injury to the lung (rare), or allergic reaction (rare). Bupivacaine has a low risk (less than 10%) of nausea, constipation, or vomiting. Epinephrine has the low risk (less than 1%) of causing a fast heartbeat or high blood pressure. Clonidine has the low risk (less than 1%) of causing a slow heartbeat or low blood pressure. Dexamethasone has the small risk (less than 1%) of causing increased blood sugar. The nerve blocks are placed into the nerves along the area of your sternal incision while you are still under anesthesia. You should discuss the risk of being in this study with the study staff.
Confidentiality and privacy	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.

Reproductive Risks and other Issues to Participating in Research

Due to unknown risks and potential harm to the unborn fetus, sexually active women of childbearing potential must use a reliable method of birth control while participating in this study. Reliable methods of birth control are: abstinence (not having sex), oral contraceptives, OrthoEvra patch, NuvaRing, intrauterine devices (IUD), Nexplanon implant, DepoProvera, tubal ligation, or vasectomy of the partner (with confirmed negative sperm counts) in a monogamous relationship (same partner). An acceptable, although less reliable, method involves the careful use of condoms and spermicidal foam or gel and/or a diaphragm with spermicide with Plan B used for any noticed condom or diaphragm failures. We encourage you to discuss this issue further with your physicians if you have any questions.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may or may not be direct benefit to you. It is anticipated that since you are receiving the nerve block, you should experience a decreased

amount of pain after your surgery compared to if you had not received it. We also hope the information learned from this study will benefit other people in the future. The benefits of participating in this study may be that your pain relief may be better than standard therapy you could receive without being in the study. Because individuals respond differently to therapy, no one can know in advance if it will be helpful in your particular case.

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 these option of receiving the normal IV and oral opioids and pain medications to treat your postoperative pain without receiving any nerve block.

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 responsibility.

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.

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 an investigator initiated clinical trial and has no outside sponsor funding the principal investigator for the conduct of this study.

What Happens if You Experience an Injury or Illness as a Result of Participating in this Study?

Atrium Health Wake Forest University Baptist Medical Center maintains limited research insurance coverage for the usual and customary medical fees for reasonable and necessary treatment of injuries or illnesses to some participants in certain research studies. To the extent research insurance coverage is available under this policy, the reasonable costs of these necessary medical services will be paid, up to a maximum of $25,000. To the extent research

coverage is not available, you or your insurance company may be charged for the costs of medical care. You may receive care at Wake Forest University Baptist Medical Center and/or Atrium Health.

If you are injured, the insurer may require information such as your name, social security number, and date of birth in order to pay for your care. This is because the insurer is required by law to report any payments made to cover the care of any persons who are members of a government insurance plan to the Department of Health and Human Services.

You do not give up any legal rights as a research participant by signing this consent form. For more information on medical treatment for research related injuries or to report a study related illness, adverse event, or injury you should call Dr. Rawad Hamzi at [redacted] or after hours at [redacted].

WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any information we get from your medical records or other facilities about your health or behaviors is considered Protected Health Information. Some of the information we will collect for this research study includes**:** age, race, ethnicity, surgical procedure, medications received, and pain scores.

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 with two factor authentication required for access.

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 including carrying out the study, determining the results of the study, making sure the study is being done correctly, providing required reports, and getting approval for new products.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; 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.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records will be kept for at least 6 years after the study is finished. At that point, any research information not already in your medical record will destroyed. Any research information entered into your medical record will be kept for as long as your medical record is kept by the Medical Center.

You can tell Dr. Hamzi 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:

Rawad Hamzi, MD, MS
[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.

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 you no longer meet inclusion criteria to participate in the study or your condition has worsened. Information that identifies you may be removed from the data that are collected as part of this study and could be used for future research or shared with others without additional consent. Clinically relevant research results will be not be directly disclosed to you but will be published in lieu of individual contact.

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. Rawad Hamzi, at [redacted] during regular business hours or after hours at [redacted] after regular business hours.

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 to keep for your records.

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