1. Protocol Title

A comparison of the analgesic effects of pectointercostal fascial plane block (PIFB) alone versus PIFB with rectus sheath block (RSB) in cardiac surgery: a prospective, randomized controlled trial.

NCT04908449

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Medical College of Wisconsin
INTRODUCTION TO THE INFORMED CONSENT

A comparison of the analgesic effects of pectointercostal fascial plane block (PIFB) alone versus PIFB with rectus sheath block (RSB) in cardiac surgery: a prospective, randomized controlled trial.

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Definitions

Pectointercostal fascial plane block (**PIFB)** – This is a nerve block that targets anterior intercostal nerves, which give sensation to the midline of the anterior chest, or around the sternum (breastbone).

Rectus sheath block (RSB) – This is a nerve block that targets anterior cutaneous nerve branches of the intercostal nerves, which give sensation to the upper abdomen.

Nerve block – An injection of medication with numbing medication, or local anesthetic, to numb up specific nerves. Usually done under ultrasound guidance. Nerve blocks are used to control pain during and after your heart surgery.

Extubation – Removal of the breathing tube and respiratory support used to provide you with oxygen and breathing assistance during and after your heart surgery.

Purpose

This project is being done to see if two nerve blocks (RSB with PIFB) decrease pain scores, opioid consumption, and improve quality of recovery after heart surgery better than just one nerve block (PIFB alone).

Length

- You will be in this research project for about 24-30 hours after extubation. Research activities will occur for about 24-30 hours after extubation.
- We would also like to follow you until you are discharged from the hospital.

Procedures

There are two groups in this procedure. One group will receive two nerve blocks: a PIFB with local anesthetic and a RSB with saline (placebo), and the other group will receive both PIFB and RSB with local anesthetic. You will be randomized (like flipping a coin) to determine which group you will be in.

List of visits:

- Our team will see you before your surgery, and then our team and/or the ICU team will ask you about your pain and recovery multiple times within the 24 hour period after surgery, at 1, 3, 6, 12, 18, and 24 hours after extubation.
- Our team will also measure your breathing with a simple breathing exercise before surgery and then at 1, 3, 12, and 24 hours after extubation.

Procedures that will occur at various visits:

Invasive Procedures

- Two nerve blocks with local anesthetic will be done in the operating room while you are asleep at the end of your surgery.

Non-invasive Procedures

- Incentive spirometry, or tests of deep breathing, will be done before your surgery and at multiple times after surgery.
- Pain assessments for 24 hours after surgery

Risks

This is a brief list of the most commonly seen side effects. The ***full consent form*** after this introduction contains a more complete list of potential research risks.

Nerve block risks:

- Bleeding
- Infection
- Allergic reaction
- Local anesthetic toxicity
- Damage to nerves, blood vessels, or other surrounding structures

- Questions about the quality of your recovery after surgery

Benefits

We don't know if this project will help you. Your condition may get better but it could stay the same or even get worse.

My Other Options

You do not have to join this project. Your other options may include:

- Joining a different project
- Routine care for this condition, which typically includes just one nerve block (PIFB) for appropriate patients
- Getting no treatment for this condition

If you have more questions about this project at any time, you can call Anne Castro, MD at 262-805-2715.

If you have questions about your rights as a participant, want to report any problems or complaints, or offer input, you can call the MCW/Froedtert Hospital Research Subject Advocate at 414-955-8844.

CONSENT TO PARTICIPATE IN RESEARCH

A1. INTRODUCTION – WHY ARE WE ASKING YOU TO PARTICIPATE?

You are being invited to participate in this research because you are having heart surgery at Froedtert.

A total of about 80 people are expected to participate in this research at Froedtert Hospital.

The Director of the project is Anne Castro, MD in the Department of Anesthesia. A research team works with Anne Castro. You can ask who these people are.

The research doctor will not receive any payment from outside institutions for carrying out this project.

A2. DO I HAVE TO PARTICIPATE?

You can decide whether to take part in this research or not. You are free to say yes or no. If you do not agree to join, or if you leave, you will not be penalized or lose any benefits that you had before starting the research project. Even if you join this project, you do not have to stay in it. You may stop at any time. Take as much time as you need to make your choice.

A research project is different from routine medical care in three ways: 1) there are extra risks that we will tell you about in this form; 2) you may have some extra medical tests and visits; 3) the research procedures, tests and visits follow a set plan that must be kept.

A3. WHY IS THIS PROJECT BEING DONE?

When patients undergo heart surgery, the surgeons have to make an incision through the sternum at the start of surgery, and at the end of surgery they need to insert tubes through the chest to let any blood or fluid drain out after surgery. Both the incision at the sternum and the chest tubes can cause pain after surgery. Patients having heart surgery at Froedtert often have nerve blocks done with numbing medication (local anesthetic) while they are asleep in the operating room to help with pain after surgery from the surgical incision. These are called pecto-intercostal fascial plane blocks, or PIFBs. This study is investigating whether adding a second nerve block, rectus sheath blocks (RSB), will help with additional pain from where the chest tubes are inserted. We will determine if the additional pain control with two nerve blocks will decrease the amount of narcotic medications you need after surgery, as well as improve your breathing and overall quality of recovery.

B1. WHAT WILL HAPPEN IF I PARTICIPATE?

Screening procedures:
If you decide to join, the research team will ask you further questions about your health history to see if you are eligible.

If the screening information shows that you meet the requirements, then you will be able to start. If the screening information shows that you cannot be in the research, you will receive the normal care for your surgery.

Research groups

Group 1 Bilateral PIFB with local pain medication and bilateral RSB with placebo (saline)

Or

Group 2 Bilateral PIFB with local pain medication and bilateral RSB with local pain medication

Saline is a fluid that would not be expected to relieve pain or harm you in any way. We will then monitor your pain and other recovery outcomes after surgery.

Because no one knows which of the interventions is best, you will be "randomized" into one of the two groups. One group will receive bilateral rectus sheath blocks with local anesthetic and one group will receive bilateral rectus sheath blocks with placebo (saline). Randomization means that you are put into a group by chance. It is like flipping a coin. You will have an equal chance of being placed in either group. Neither you nor the research doctor can choose what group you will be in.

Neither you nor your research doctor can know which drug you will get until the research is over. A computer program chooses which group you are in, and the fluid for the injection in each group will look the same. In an emergency, your research doctor can find out which drug you are taking.

If you join this project, you will be given one of two interventions without knowing exactly which one (a "blinded" project). If you ask to see your health records during this "blinded" project, the research team cannot tell you which medication (local anesthetic or placebo) you are being given. This is because the research team also remains "blinded" about which medication the sponsor has randomly assigned to you. You would have to wait until the time given below. We cannot do the project unless you agree. However, if the blinded information is needed to treat you, it will be provided to the research doctor.

- What are the blinded options? You will get one of these drugs/interventions: saline placebo or local anesthetic (bupivacaine) will be injected into the rectus sheath blocks.

- When can you find out which medication you were given? You can find out after all data collection is completed, which we anticipate to be approximately one year after the start of the study.

For this project, the research team will assign you a unique code, such as a number. When analyzing your data, the research doctor will use your unique code instead of other information that could easily identify you.

The data that is recorded with your unique code rather than your name is called "key-coded data". The research doctor will keep a confidential list linking your name to your code and only the research doctor and authorized research team members will have access to this list.

Summary of Procedures:

Invasive Procedures

- Two nerve blocks with local anesthetic will be done in the operating room while you are asleep at the end of your surgery.

Non-invasive Procedures

- Incentive spirometry, or tests of deep breathing, will be done before your surgery and at multiple timepoints (1, 3, 12, and 24 hours) after extubation.
- Pain scores: you will be asked about your pain at 1, 3, 6, 12, 18, and 24 hours after extubation
- Quality of recovery: you will be asked various questions about how you are doing/your general recovery 24 hours after being extubated, with a range of 18-30 hours to prevent waking you from sleep

B2. HOW LONG WILL I BE IN THE PROJECT?

⇒ You will be in this research project for about 24-30 hours after extubation, and data about your recovery will be reviewed until the time of your hospital discharge.

B3. CAN I STOP BEING IN THE PROJECT?

You are free to withdraw from the project at any time. If you leave, your regular medical care will not change. If you are thinking about leaving, please tell the research doctor.

The research doctor may take you out of this project at any time. This would happen if:

- They think it is in your best interest.
- You do not follow the project rules.
- The whole project is stopped.

If this happens, the research doctor will tell you.

C1. WHAT HEALTH RISKS OR PROBLEMS CAN I EXPECT FROM THE PROJECT?

There are risks to taking part in any research project. There is a risk that the study medication does not help your condition or may make it worse. There also may be problems (side effects) we do not know about yet, from local anesthetic itself, or how it combines with other drugs you are taking. If we learn about new important side effects, we will tell you.

We watch everyone in the project for problems (side effects). **You need to tell the research doctor or a member of the research team immediately if you experience any problems, side effects, or changes in your health.** As you will be in the hospital recovering from surgery for several days after surgery, your cardiothoracic surgery team will be monitoring you closely for any concerning symptoms, including evidence of allergic reaction to medication, infection, or bleeding at the site of nerve block injections.

C2. RISKS OF NERVE BLOCKS

Nerve blocks may cause problems (side effects). Side effects may be mild or very serious. Some can last a long time or never go away.

Side effects related to nerve blocks with saline (placebo) include: bleeding, minor pain or discomfort at the site, injury to nearby structures such as arteries, veins nerves, or the lung, muscle soreness, infection, allergy or adverse drug reaction.

Side effects related to nerve blocks with bupivacaine with epinephrine include: bleeding, minor pain or discomfort at the site, injury to nearby structures such as arteries, veins nerves, or the lung, residual numbness, weakness, muscle soreness, infection, allergy or adverse drug reaction, increased heart rate or blood pressure related to intravascular absorption of epinephrine, or intravascular injection of local anesthetic causing seizure or cardiac arrest.

C3. OTHER RISKS OF THIS RESEARCH PROJECT

Other procedures that are part of the research also involve some risks:

1. Incentive spirometry: This is a simple tool that allows measurement of breathing capacity. It is often used after surgery to help exercise your lungs. The principle risk is that deep breathing while performing incentive spirometry may be associated with temporary discomfort.
2. Completing postoperative pain assessments and the Quality of Recovery score: This will involve being asked questions about your pain and general questions about how you are doing by your nurses or the study team. Risks of these assessments include discomfort with answering questions and possible loss of confidentiality, as noted below.

Another risk may be loss of confidentiality. Every effort will be made to keep your research records confidential but we cannot guarantee it. Depending on the kind of information being collected, if your research information were accidentally seen, it might be used in a way that could embarrass you or affect your ability to get insurance. If you have questions, you can talk to the project director about whether this could apply to you.

C4. REPRODUCTIVE RISKS

Risks to subjects who could become pregnant
We do not know if the nerve blocks harm to a baby, so we do not want anyone who might be pregnant to enter the project. A pregnancy test will be given on the morning of surgery to all women of child-bearing age, consistent with standard of care prior to elective surgery, and all patients with positive pregnancy tests will not be eligible to participate in the study.

C5. ARE THERE ANY BENEFITS TO TAKING PART IN THE PROJECT?

If you receive the rectus sheath blocks with the numbing medication, you may have improved pain control after surgery, requiring you to need less other medications to treat pain. We hope that in the future the information learned from this study will benefit other people undergoing heart surgery. You are not expected to receive any direct medical benefit above standard of care if you are in the placebo group.

D1. ARE THERE ANY COSTS TO BEING IN THE PROJECT?

⇒ Most of the medical care that you will receive in this project is considered routine care for your condition and would be recommended whether or not you join the project. Costs for routine care will be billed to you or your insurance carrier. For routine clinical care, you will be responsible for paying any copayment, coinsurance, or deductible that is required by your insurance carrier. Activities / costs that are part of the project will not be billed to you or your insurance company. These are the cost of local anesthetic or saline used in the rectus sheath block and the RSB procedure. These also include additional incentive spirometry checks, pain score assessments, and the Quality of Recovery survey. Some insurers will not pay for drugs, tests or hospitalization that are part of research, so check with your insurer before you join this project. If you have questions regarding costs, please contact Dr. Castro.

If you participate in this research, the costs of any necessary emergency medical treatment in the event of a research-related injury will be billed to you or your health insurance.

D2. WILL I BE PAID FOR PARTICIPATING IN THE PROJECT?

There is no payment for being in this project.

Sponsor, other researchers, or research companies may patent or sell products, discoveries and data or information that result from this research. The PI will not pay you if this happens. You will not receive any payment or commercial rights for products, data, discoveries, or materials gained or produced from your health information.

D3. WHAT OTHER HEALTHCARE CHOICES DO I HAVE?

You do not have to join this project. You are free to say yes or no. If you do not join this project, your research doctor can discuss other healthcare choices with you.

Your other choices may include:

- Routine care for your heart surgery, which typically includes just one nerve block (PIFB).
- Joining a different research project

The research doctor can explain both the possible benefits and the risks of other options that are available to you.

D4. WILL I BE GIVEN NEW INFORMATION ABOUT THE PROJECT?

If we learn any important new information about the intervention that might change your mind about being in the project, we will tell you about it right away. You can then decide if you want to stay in the project.

D5. WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THE PROJECT?

Emergency medical treatment for injuries directly related to your participation in this research project will be provided to you. You or your health insurance will be billed for the costs of this emergency treatment. MCW will decide on a case by case basis if they will reimburse you or your insurer for emergency treatment costs. If your research-related injury requires medical care beyond this emergency treatment, you or your insurer will be responsible for the costs of this follow-up care.

At this time, there is no plan for any additional financial payments.

If you believe that you have been injured because of your participation in this project, contact the research doctors right away. Contact information: Anne Castro, 414-805-2715.

Nothing in this consent form affects any legal rights you may have nor does it release the investigator, the sponsor, the institution, or its agents from liability for negligence.

D6. WHO CAN ANSWER MY QUESTIONS ABOUT THE PROJECT?

- If you have more questions about this project at any time, you can call Anne Castro at 414-805-2715
- If you have questions about your rights as a research participant, want to report any problems or complaints, or offer input, you can call the MCW/Froedtert Hospital Research Subject Advocate at 414-955-8844.

E. PERMISSION TO COLLECT, USE AND SHARE HEALTH INFORMATION

E1. What health information will be collected and used for this project?

To be in this research project, the research team needs your permission to access, collect and use some of your health information. If you say no, you cannot be in the project. This information may come from questions we ask, forms we ask you to fill out, or your medical record, as described below. We will only collect and use information needed for the project.

The protected health information (PHI) originates from services you will or have received at one or more of the following locations: the Medical College of Wisconsin (MCW); Versiti, Inc.; Children's Hospital of Wisconsin (CHW); any Froedtert Health Affiliate- Froedtert Hospital (FH), Inc.; Froedtert Menomonee Falls Hospital; Froedtert West Bend Hospital; Froedtert & The Medical College of Wisconsin Community Physicians Clinics, Inc. (FMCWCP); the West Bend Surgery Center, LLC; and the Froedtert Surgery Center, LLC.

The health information to be collected and used for this project is:

- ⇨ Medical records of the care you receive for this project until hospital discharge
- ⇨ Medical records pertaining to any possible complications after your surgery
- ⇨ Medical records to be used to determine your eligibility for the study

E2. Who will see the health information collected for this project?

We may record your research information, including results of tests and procedures done for research, in your Froedtert Hospital and/or Medical College of Wisconsin medical record. As a result, this research information may be seen by people allowed to see your medical records for healthcare operations or treatment, by those you allow to see your medical records by giving written permission, and by others when required by law.

We will not use your personal health information for a different project without your permission or the permission of a hospital research review board (IRB). Once all personal information is removed from your health information, the information may be used for future research or distributed to another investigator for future research without additional informed consent from you or your legally authorized representative. The information might also be used or released for other purposes without asking you. Results of the project may be presented in public talks or written articles, but no information will be presented that identifies you.

The only MCW/Froedtert Hospital employees allowed to handle your health information are those on the research team, those on the Institutional Review Board (IRB) and those who check on the research activities to make sure the hospital's rules are followed.
If the costs of any necessary emergency medical treatment in the event of a research-related injury are billed to your health insurance, your health information may need to be disclosed to the insurer for billing purposes.

Because this project involves the use of drugs and/or devices, the FDA also has the right to inspect all project records.

E3. What are the risks of sharing this health information?

One risk of taking part in a research project is that more people will handle your personal health information collected for this project. The research team will make every effort to protect the information and keep it confidential, but it is possible that an unauthorized person might see it. If you have questions, you can talk to the research doctor about whether this could apply to you.

E4. How long will you keep the health information for this project?

If you sign this form, we plan to keep your information for 10 years after the research project ends in case we need to check it again for this project.

E5. Can I cancel my permission to share this health information?

If you change your mind later and do not want us to collect or share your health information, you need to send a letter to Anne Castro at *Department of Anesthesia, 9200 W. Wisconsin Ave, Milwaukee WI 53226*. The letter must say that you have changed your mind and do not want the researcher to collect and share your health information. At that time, we will decide that you cannot continue to be part of the project. We may still use the information we have already collected.

F1. FOR MORE INFORMATION ABOUT THE PROJECT

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.

You can look up this project by referring to the ClinicalTrials.gov number NCT04908449 or by asking the research team for a printed copy.

CONSENT TO PARTICIPATE

By signing my name below, I confirm the following:

- I have read (or had read to me) this entire consent document. All of my questions have been answered to my satisfaction.
- The project's purpose, procedures, risks and possible benefits have been explained to me.
- I agree to let the research team use and share the health information and other information gathered for this project.
- I voluntarily agree to participate in this research project. I agree to follow the procedures as directed. I have been told that I can stop at any time.

IMPORTANT: You will receive a signed and dated copy of this consent form. Please keep it where you can find it easily. It will help you remember what we discussed today.

Subject's Name *please print*	**Subject's Signature**	**Date**

*** Name of person discussing/ obtaining consent** *please print*	**Signature of person discussing/obtaining consent**	**Date**

** A member of the research team trained and authorized by the Principal Investigator to act on her/his behalf in obtaining informed consent according to the protocol. The Principal Investigator is responsible and accountable for the research project.*