**TITLE: Randomized Clinical Trial Comparing Analgesia and Plasma Pharmacokinetics of Lidocaine administered by Erector Spinae Plane Blocks vs. Intravenous Routes Following Open Heart Surgery: An Equivalence Study**

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## INFORMED CONSENT DOCUMENT

**Project Title: Randomized clinical trial comparing analgesia and plasma pharmacokinetics of lidocaine administered by Erector Spinae Plane Blocks vs. Intravenous routes following open heart surgery: An equivalence study**

**Principal Investigator:** **Archit Sharma, MD MBA**

**Research Team Contact:** **Archit Sharma, MD MBA**
[redacted]

This consent form describes the research study to help you decide if you want to participate. This form provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights as a research subject.

- If you have any questions about or do not understand something in this form, you should ask the research team for more information.
- You should discuss your participation with anyone you choose such as family or friends.
- Do not agree to participate in this study unless the research team has answered your questions, and you decide that you want to be part of this study.

### WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We are inviting you to participate in this research study because you are scheduled to undergo cardiac surgery by your cardiac surgeon. The surgical procedures included in this study are either a valve replacement or CABG (coronary artery bypass grafting).

The purpose of this research study is to evaluate the effectiveness, mechanism and safety of lidocaine (analgesic medication) in controlling pain after cardiac surgical procedures. During the past decade, different approaches have been developed to provide this pain relief. One method developed is called an erector spinae plain (ESP) block in which several large muscles in your back/trunk receive analgesic medication through a small catheter (tube) inserted in your back area by your anesthesiologist. It is thought the medication spreads locally in that region (the area around your spinal cord also called paravertebral space) and numbs the nerves in the area which helps control the pain. It is also known that sometimes the medication delivered through the catheters into the paravertebral space can get into your blood stream and the level can be measured using standard laboratory tests. Because everyone's anatomy around their spinal column/cord is different, we don't fully understand the mechanism of how these medications provide relief and requires further evaluation.

To evaluate, the research team will compare two different approaches. After you arrive in the CV-ICU area, you will either receive lidocaine pain medication either through the catheter (ESP block) or through your IV. You will continue to receive your other pain medications as prescribed by your doctor. Blood samples will be drawn and the concentration of lidocaine will be measured. The nurses routinely ask and record what your pain level is and this will be recorded in your medical record. The research team will collect this information and share our findings. Your personal and medical information will be kept confidential.

## HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 70 people will take part in this study conducted by investigators at the University of Iowa

## HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for approximately 72 hours (3 days).

- Blood samples for this study will be drawn with the last being 24 hours after medication dosing
- Pain score will be collected by nursing staff every 2-4 hours. The research team will retrieve the pain scores collected for the first 48 hours.
- The amount of pain medications used will be measured for the first 72 postoperative hours.

## WHAT WILL HAPPEN DURING THIS STUDY?

- If you agree to participate in this study, you will be randomly assigned to receive lidocaine pain medication either by ESP block or intravenously (IV). This means that whichever approach you receive will be determined purely by chance, like flipping a coin. You will have a 50/50 chance of receiving the medication by either approach. You will only be assigned to one technique method.

- The ESP catheter will be inserted either pre- or post-operatively and taped in place to your back to receive the medication. This is dependent on how you were randomized.

- For both groups, you will be positioned to lay on your back.

- If you randomize to the ESP group, you will receive lidocaine medication through the ESP catheter that was placed in your back. However, if you randomized to the opposite group, you will receive the lidocaine medication through an IV.

- Blood samples will be drawn at different times during approximately the first 24 hours you are in CV-ICU. The samples will be used to determine what the lidocaine concentration is in your blood. About 10 ml (about 2 teaspoons) of blood will be drawn each time at 5, 30, 60 and 120 minutes, 6 and 24 postoperative hours.

- Nursing staff routinely report (every 2-4 hours) how much pain you are experiencing and record this information in your medical record. The research team will use this data during their assessments.

- After your surgical procedure, you will receive opioid medications as prescribed by your physician. No changes will be made to what your doctor has ordered. The research team will look at how much opioid medication was required to keep you comfortable during the first 72 hours after your surgical procedure and use this information during their analysis.

## WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

**Life Threatening**

- No foreseeable risk

**Serious**

- Systemic toxicity due to the concentrations of the medication – causing irregular heart rhythm, low blood pressure or seizures
- Nerve injury when placing ESP catheters- leading to local irritation or pain
- Puncture of the lung with a needle
- Failure to provide adequate pain relief

**Mild**

- Allergic reaction to adhesive materials used to secure the catheters to your skin.
- Bruising during placement of ESP catheter
- Infection at catheter placement site

While you are enrolled in this study, you will receive the medication, lidocaine. You may experience none, some or all the side effects described above. This medication will be given to you in the Cardiac ICU where you will be monitored closely for any side effects by healthcare staff. The healthcare staff can prescribe corrective measures if required.

## WHAT ARE THE BENEFITS OF THIS STUDY?

We don't know if you will benefit from being in this study.

However, we hope that, in the future, other people might benefit from this study because the knowledge learned will help physicians provide the best care options to control the pain for patients who undergo similar cardiac surgical procedures.

## WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any additional costs for being in this research study.

You and/or your medical/hospital insurance carrier will remain responsible for your regular medical care expenses.

## WILL I BE PAID FOR PARTICIPATING?

You will not be paid for being in this research study.

## WHO IS FUNDING THIS STUDY?

The University and the research team are receiving no payments from other agencies, organizations, or companies to conduct this research study.

The University of Iowa Center for Advancement-Anesthesia Research Institute has provided funding to cover the costs of study medications and supplies.

## WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?

- If you are injured or become ill from taking part in this study, medical treatment is available at the University of Iowa Hospitals and Clinics.
- The University of Iowa does not plan to provide free medical care or payment for treatment of any illness or injury resulting from this study unless it is the direct result of proven negligence by a University of Iowa employee.
- If you experience a research-related illness or injury, you and/or your medical or hospital insurance carrier will be responsible for the cost of treatment.

## WHAT ABOUT CONFIDENTIALITY?

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- federal government regulatory agencies,
- auditing departments of the University of Iowa, and
- the University of Iowa Institutional Review Board (a committee that reviews and approves research studies)

To help protect your confidentiality, we will collect only the minimal data required to do this study. All patient information will be stored on a hospital security encrypted computer/server and only authorized members of the research team will have access. Electronic data is stored on password protected computer. Paper data is kept in a locked office. If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified.

The University of Iowa Hospitals and Clinics generally requires that we document your participation in research occurring in a University of Iowa Health Care facility. This documentation will be in either your medical record or a database maintained on behalf of the institution reflecting that you are participating in this study. The information included will provide contact information for the research team as well as information about the risks associated with this study. We will keep this Informed Consent Document in our research files; it will not be placed in your medical record chart.

## WILL MY HEALTH INFORMATION BE USED DURING THIS STUDY?

The Federal Health Insurance Portability and Accountability Act (HIPAA) requires your health care provider to obtain your permission for the research team to access or create "protected health information" about you for purposes of this research study. Protected health information is information that personally identifies you and relates to your past, present, or future physical or mental health condition or care. We will access or create health information about you, as described in this document, for purposes of this research study. Once your health care provider has disclosed your protected health information to us, it may no longer be protected by the Federal HIPAA privacy regulations, but we will continue to protect your confidentiality as described under "Confidentiality."

We may share your health information related to this study with other parties including federal government regulatory agencies, the University of Iowa Institutional Review Boards and support staff.

You cannot participate in this study unless you permit us to use your protected health information. If you choose *not* to allow us to use your protected health information, we will discuss any non-research alternatives available to you. Your decision will not affect your right to medical care that is not research related. Your signature on this Consent Document authorizes your health care provider to give us permission to use or create health information about you.

Although you may not be allowed to see study information until after this study is over, you may be given access to your health care records by contacting your health care provider. Your permission for us to access or create protected health information about you for purposes of this study has no expiration date. You may withdraw your permission for us to use your health information for this research study by sending a written notice to Archit Sharma, MD, University of Iowa Hospitals and Clinics, Department of Anesthesia, 200 Hawkins Drive, Iowa City, IA 52242. However, we may still use your health information that was collected before withdrawing your permission. Also, if we have sent your health information to a third party, such as the study sponsor, or we have removed your identifying information, it may not be possible to prevent its future use. You will receive a copy of this signed document.

## IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify

## What if I Decide to Drop Out of the Study?

Leaving the study early may cause you to experience the following harms or discomforts: Pain due to your surgical procedure.

FOR IRB USE ONLY
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**Can Someone Else End my Participation in this Study?**
Under certain circumstances, the researchers might decide to end your participation in this research study earlier than planned. This might happen because in your physician's judgement it would not be safe for you to continue.

**WHAT IF I HAVE QUESTIONS?**

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Archit Sharma, MD [redacted]. If you experience a research-related injury, please contact: Archit Sharma, MD [redacted].

If you have questions, concerns, or complaints about your rights as a research subject or about research related injury, please contact the Human Subjects Office, 105 Hardin Library for the Health Sciences, 600 Newton Rd, The University of Iowa, Iowa City, IA 52242-1098, (319) 335-6564, or e-mail irb@uiowa.edu. General information about being a research subject can be found by clicking "Info for Public" on the Human Subjects Office web site, http://hso.research.uiowa.edu/. To offer input about your experiences as a research subject or to speak to someone other than the research staff, call the Human Subjects Office at the number above.

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This Informed Consent Document is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by signing this Informed Consent Document. Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a copy of this form.

Subject's Name (printed): _____

_____ _____
(Signature of Subject) (Date)

**Statement of Person Who Obtained Consent**

I have discussed the above points with the subject or, where appropriate, with the subject's legally authorized representative. It is my opinion that the subject understands the risks, benefits, and procedures involved with participation in this research study.

_____ _____
(Signature of Person who Obtained Consent) (Date)