Official Title: Improving Pain Control in Paraesophageal Hernia Repair: Intravenous Lidocaine Versus Placebo

NCT04096170

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ATRIUM HEALTH
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Sponsor / Study Title:	**Atrium Health-Department of Surgery / Improving Pain Control in Paraesophageal Hernia Repair: Intravenous Lidocaine Versus Placebo**
Protocol Number:	**(06-18-03)**
Principal Investigator: (Study Doctor)	**Paul D. Colavita, MD**
Telephone:	[redacted]
Address:	**Atrium Health** **Carolinas Medical Center** **Department of Surgery** [redacted]

Please read this form carefully. Take time to ask the study doctor or study staff as many questions about the study as you would like. The study doctor or study staff can explain words or information that you do not understand. Reading this form and talking to the study doctor or study staff may help you decide whether to take part or not. If you decide to take part in this study, you must sign and date your name at the end of this form. You cannot take part in this research study until you sign and date this form.

SUMMARY

You are invited to participate in a research study. The purpose of this research study is to improve the recovery of patients after undergoing paraesophageal hernia repair. You are invited to be in this study because diagnosed with a paraesophageal hernia. Your participation in this research study will involve 3 visits and last about 6 months.

Participation in this study will involve being randomized to one of two groups and receiving IV lidocaine or a placebo for pain control. All research studies involve some risks. A risk to this study that you should be aware of is the need for other or additional pain medication. 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. 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].
If you have any questions, suggestions, or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [redacted].

INTRODUCTION

Dr. Paul Colavita is asking you to participate in this research study to improve the recovery of patients after undergoing paraesophageal hernia repair at the Division of Gastrointestinal and Minimally Invasive Surgery and Atrium Health. You are being asked to take part because you have been diagnosed with a paraesophageal hernia. The purpose of this study is to assess the pain control, and improvement and recovery made after surgery with intravenous (into a vein) lidocaine during surgery. You will be one of approximately 50 subjects involved in this research project at

Atrium Health.

HOW THE STUDY WORKS

If you agree to be in the study, you would be randomized to one of two study treatment methods. Being randomized means that you are put in a group by a chance process, like flipping a coin. You won't know what group you are in. Your chance of receiving one of the study treatments is one in two. Currently, most paraesophageal patients receive intravenous (IV) and oral opioid pain medication such as morphine. Opioid pain medications have known side effects such as nausea and constipation. It is known that reducing the amount of medication taken can reduce the chances of experiencing these side effects. In the past, IV lidocaine has been shown to improve patients' pain scores. Presently, it is unclear if IV Lidocaine will reduce the amount of opioid pain medication patients require to achieve adequate pain control. You will either receive Perioperative (around the time of surgery) IV lidocaine or a placebo. Postoperatively, you will receive standard pain medications.

There are two arms in this study. You will receive either perioperative IV lidocaine or a placebo. We do not expect that IV lidocaine will eliminate the need for opioids for pain control after surgery, but the degree to which this is reduced is an important measure of the effectiveness of which arm you were in.

Subjects in the IV Lidocaine study treatment method will receive IV Lidocaine in the operating room and in the Recovery Room for one hour. After that, subjects in the IV Lidocaine arm will be given the usual pain medications prescribed by your surgeon.

Subjects in the placebo arm, will receive an infusion of IV "Normal Saline" during and after the operation. This will be the same amount of fluid given as subjects receiving the IV Lidocaine.

The study of IV Lidocaine is a subset of an Enhanced Recovery After Surgery (ERAS) program. ERAS is a program we have initiated to help people recover from ventral hernia surgery more quickly, by limiting narcotics and encouraging early ambulation (getting up and moving about) and early feeding with the goal of determining whether surgical patients may be able to recover faster. ERAS has been used with great success in colorectal surgery. Our surgeons may counsel you on healthy weight loss if needed. You may also drink a clear liquid up to 2 hours before surgery. After surgery, your diet will be gradually advanced as you recover from surgery and you will be allowed to drink post operatively should you wish. Additionally, you will be asked to complete questionnaires on your experiences following surgery up to 6 months post operatively. These questionnaires will be mailed to you or given when you visit in clinic.

Your participation in this study will last approximately 6 months.

RISKS

We do not expect that IV lidocaine will eliminate the need for opioids for pain control after surgery. All patients are routinely assessed for pain, regardless of your participation in this study. We adequately control all patient's pain post operatively by routine assessment of pain level and treating with medication until controlled.

The most common adverse reactions (side effects) following administration of intravenous IV Lidocaine are:

- Perioral (around the mouth) numbness,
- Nausea,
- Vomiting.

The side effects of lidocaine are directly related to the serum lidocaine level. Side effects are rare at serum levels within the 2-6 mcg/mL range. Side effects are more

pronounced in subjects with liver dysfunction, and pulmonary (related to the lungs) diseases where the predominant problem is carbon dioxide retention, and congestive heart failure. Side effects are described as follows:

- Mild (at serum levels 3-8 mcg/mL) numbness and tingling in the fingers and toes, numbness and unusual sensations around the mouth, a metallic taste in the mouth, ringing in the ears, or lightheadedness and dizziness.
- Moderate side effects (at serum levels 8-12 mcg/mL) includes mild side effects with the addition of nausea and vomiting, severe dizziness, decreased hearing, tremors, changes in blood pressure and pulse. Nausea and vomiting without other lidocaine side effects in the postoperative setting is unlikely to be related to the lidocaine.
- Severe side effects (at serum levels greater than 12 mcg/mL) may include drowsiness confusion, muscle twitching, convulsions, loss of consciousness, cardiac arrhythmias (irregular heartbeat), cardiac arrest.

Side effects of narcotic pain medication include:

- Itching
- Nausea
- Vomiting
- Constipation
- Drowsiness

An additional risk to you is the release of information from your health records. The study doctor and study site will protect your records so that your name, address, and phone number will be kept private. Nevertheless, there is still a small risk of a breach of confidentiality.

It involves data collection from past medical records and depends upon patient identifiers for data collection. HIPAA compliance in clinical and pathologic data

handling will ensure protection of patients' rights to privacy. Data access will be restricted to those involved in data collection or analysis.

Placebo Risks

If you are in the group that is assigned placebo (the medically inactive substance), your symptoms may not improve or may worsen. Even if you are in the group that gets the IV Lidocaine during the study, your symptoms may not improve or may worsen.

Allergic Reaction Risks

As with taking any drug, there is a risk of allergic reaction. If you have a very serious allergic reaction, you may be at risk of death. Some symptoms of allergic reactions are:

- Rash
- Wheezing and difficulty breathing
- Dizziness and fainting
- Swelling around the mouth, throat or eyes
- A fast pulse
- Sweating

Please seek treatment immediately and tell the study doctor and study staff if you have any of these symptoms, or any other side effects, during the study.

Unknown Risks

You might have side effects or discomforts that are not listed in this form. Some side effects may not be known yet. New ones could happen to you. Tell the study doctor or study staff right away if you have any problems.

BENEFITS

This study may or may not improve your condition. The information gained from your participation may benefit others with your condition and may show that the study treatment may allow subjects to feel better faster, return to their daily activities faster, and return home from the hospital more quickly.

ALTERNATIVE PROCEDURE/TREATMENT

If you choose not to participate in this study, your hernia will be treated with standard of care procedures. You have the option to proceed with the surgery, but you will not receive additional treatments that are not standard of care. You may also decide that you do not want surgery and you have the option to continue medical management. You should talk with your study doctor about your options.

ADDITIONAL COST

You will not be charged for the cost of the IV lidocaine.

Other additional charges will not be covered by Atrium Health . Your insurance company may not pay for research treatments. You may wish to discuss coverage with your insurance company before agreeing to participate in this research study.

COMPENSATION

There will be no monetary compensation for participating in this study.

STUDY STAFF PAYMENT/FINANCIAL DISCLOSURE

None of the doctors asking you to participate in this study has received or will receive money or other benefits for personal use from the study sponsor. However, the sponsor will give money or other benefits to a research fund, foundation, educational institution, or other organization with which the doctor or study staff is associated.

COMPENSATION FOR INJURY

In the event that you are harmed as a result of your participation in this study, we will provide or arrange for treatment as necessary. This treatment, as well as other medical expenses, will be billed to you or your insurance company in the usual manner. You do not waive any legal rights by signing this consent form.

If you become ill or are hurt while you are in the study, get the medical care that you need right away.

BEING A STUDY VOLUNTEER AND WITHDRAWING FROM THE STUDY

Your participation in this study is completely voluntary. You should feel under no pressure to be in the study. If you decide not to be in the study, which will not in any way 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.

- You may always say no. You do not have to take part in the study.
- If you start a study, you may stop at any time. You do not need to give a reason.
- If you do not want to be in a study or you stop the study at a later time, you will not be penalized or lose any benefits.
- If you stop, you should tell the study staff and follow the instructions they may give you.

Your part in the research may stop at any time for any reason, such as:

- The sponsor or the study doctor decides to stop the study.
- The sponsor or the study doctor decides to stop your part in the study for your safety.
- You need additional medicine.

- You do not follow the study rules.
- You have a new injury or illness.
- You decide to stop.

You may be asked to stop the study even if you do not want to stop.

NEW INFORMATION ABOUT THE STUDY

You will be told about any new information found during the study that may affect whether you want to continue to take part.

CONFIDENTIALITY

The records of this study will be kept private. In any sort of report, we might publish, we will not include any information that will make it possible to identify a patient. Your record for this study may, however, be reviewed and/or photocopied by Atrium Health, or by representatives of the Food and Drug Administration or other government agencies. To that extent, confidentiality is not absolute.

WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any new information we collect from you and/or information we get from your medical records or other facilities]about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes: demographics, preoperative lab values, intraoperative and perioperative variables, postoperative outcomes and pain reported by VAS. total opioid analgesia administered, time from surgery to a clear liquid diet, time from surgery to a post-fundoplication diet, time to return of bowel function, length of stay, pain/VAS scores at 6 hours postoperatively, pain/VAS scores on each post-operative day until discharge, pain/VAS scores at 2 and 4 weeks, and pain/VAS scores at 6 months, infectious complications (urinary tract infections as well as surgical site infections, deep organ space infections, pneumonia), and non-

infectious complications (stroke, myocardial infarction, respiratory failure, post-op bleeding, unplanned return to the OR, acute renal failure, death, etc.).

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 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.

Monitors, auditors, IRB or other regulatory agencies will be granted direct access to your medical record for verification of clinical trial procedures or data to the extent permitted by other applicable laws. These monitors, auditors, and other individuals are also required to maintain the confidentiality of your protected health information.

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 six years after the study is finished. At that time any research information not already in your medical record will either be destroyed or it will be de-identified.

You can tell Dr. Colavita 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:

Dr. Paul Colavita
[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.

FINANCIAL INTEREST OF INVESTIGATOR

The doctors will receive no financial benefit in any form by asking you to participate in this 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, Todd Heniford at [redacted]

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

Legally Authorized Representative Name (Print):_____

The above named Legally Authorized Representative has legal authority to act for the research subject based upon (specify health care power of attorney, spouse, parent, etc.)

Relationship to the Subject:_____

Legal Representative Signature: _____ Date:_____ Time:_____ am pm