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CONSENT FORM

Reducing Postoperative Opioids in Patients Undergoing Laproscopic Hiatal Hernia

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Sponsor: Departments of Anesthesia and Surgery

The box below highlights key information about this research for you to consider when making a decision whether or not to participate. Carefully consider this information and the more detailed information provided below the box. Please ask questions about any of the information you do not understand before you decide whether to participate.

Key Information for You to Consider

- **Voluntary Consent.** You are being asked to volunteer for a research study. It is up to you whether you choose to participate or not. There will be no penalty or loss of benefits to which you are otherwise entitled if you choose not to participate or discontinue participation.
- **Purpose.** The purpose of this study is to see if a person undergoing surgery to treat a hiatal hernia will have a difference in the amount of pain medications (opioids) used after discharge when having an Opioid Based Anesthesia (OBA) approach in the operating room compared to an Opioid Sparing Anesthesia (OSA) approach, where the focus is to use other pain medications than opioids to reduce your pain. While most patients undergoing hiatal hernia surgery go home one day after surgery, opioids can cause nausea, vomiting, and bloating that may increase the time to recover in the hospital. Specifically, the study will compare the number of patients in each group that require any opioids for pain relief after discharge to home, the level of pain felt after surgery, the amount of opioids taken during the hospital stay, the level of nausea/vomiting occurring after the surgery, duration of stay in the post anesthesia care unit (PACU) and hospital, if there is readmittance to the hospital or a surgery is required again that is related to this surgery, the number of emergency room visits within 30 days of leaving the hospital, the cost of the hospital stay, and the amount of times the surgeon's office is contacted regarding any severe pain.
- **Duration.** It is expected that your participation will last in this study from the time you sign the consent from prior to surgery to thirty days after your surgery. Various aspects of your health and recovery will be recorded until 30 days after your surgery.
- **Procedures and Activities.** If you join this study, you will be randomly assigned to receive the OSA or OBA protocol during your surgery. Following your surgery, you will

be asked to fill out various surveys regarding your pain level and the medication you have taken.

- **Risks.** All medications used in this study are drugs commonly used in anesthesia practice.
- **Benefits.** We hope that a decrease in the amount of opioids during your surgery will result in a shorter stay in the hospital and the potential to not experience nausea/retching. However, there is no guarantee of these possible benefits, and the purpose of the study is to test if there are any benefits to OSA compared to OBA.
- **Alternatives.** Participation is voluntary and the only alternative is to not participate. Non-study participants can discuss their anesthesia regimen with their provider.

Detailed Information about this Study:

Introduction:

You are being asked to volunteer for this clinical research study because you are having a hiatal hernia repair surgery at Endeavor Health. This consent form gives you information about the study so that you can talk about it with your doctor and/or family. You are being given this information to help you make your decision. If you have any questions, you can ask the study doctor or staff.

Why is this Study Being Done?

At Endeavor, patients undergoing anesthesia receive a number of different drugs from their anesthesia care providers. Opioids are frequently used as a part of routine anesthesia to reduce pain both during and after surgery. However, opioids can cause nausea, vomiting, inability to go to the bathroom, sleepiness and problems with breathing. Patients undergoing hiatal hernia repair may experience these side effects when opioid based anesthesia is used. A recent study suggested that using other pain medications during surgery may reduce the need for opioids during and after surgery and reduce the length of stay in the hospital. The purpose of this study is to compare recovery and the use of opioids in patients who undergo hiatal hernia repair who receive an opioid sparing anesthesia protocol (OSA) vs. the opioid based anesthesia (OBA) protocol, routinely used for this procedure.

All medications involved in both the OSA and OBA protocols are approved by the Food and Drug Administration (FDA) for anesthesia and the protocols have been designed by a multidisciplinary team of anesthesia professionals, surgeons, and pharmacists.

This study will include a total of 75 subjects. Of those subjects, all will be from Endeavor Health (Endeavor).

What Will Happen During the Study?

If you agree to participate in this study, you will be asked to sign this consent form before any research-related activities are done.

Prior to surgery you will be randomly assigned, like the flip of a coin, to one of two groups. In this study, you will have a 50% chance of being assigned to the OSA or OBA group. The anesthesia providers will be the only people who know to which group you have been assigned. Neither you nor your surgeon will know which protocol you receive.

After surgery, you will be transferred to the Post Anesthesia Care Unit (PACU) where you will be observed by a nurse and treated for pain and any other affects you may experience after surgery. If you are in the opioid sparing group you will also be provided a pain medication (ketamine) through your intravenous line continuously until you are discharged from the PACU. This medication is used both during and after other surgeries to reduce the amount of opioids patients take. If you are in the opioid based group, you will receive saline (salt water) through your IV line that looks like pain medication (ketamine) in the opioid sparing group during your stay in the post anesthesia care unit. No matter which group you are randomly assigned to, any additional pain will be addressed by a standard PACU pain order set ordered by your anesthesiologist. Following discharge from the PACU, you will follow the normal instructions from your surgeon both in the hospital and at home, and have the same medications available as needed for pain.

You will be asked to fill out online surveys regarding your pain levels and medications taken for pain once a day from the day you are discharged from the hospital, through the 7th day following your surgery. It is expected to take less than 5 minutes daily to complete the surveys.

Additionally the research team will collect information about you for the purposes of this research.

If you consent to this study, the study doctor and/or study staff will collect the following information about you:

- Medical history, surgical history, age, sex, height, weight, information about your surgery , and a list of any prior and current medications that you are taking. This information will be collected for screening/eligibility purposes and to ensure that you meet all the study inclusion criteria.
- Data obtained before, during, or after your surgery including what pain medications you are given in the hospital or took at home, the amount of pain you have after surgery, the length of your stay in the PACU and hospital, any occurrence of nausea and vomiting after surgery, if you have to go back to the hospital or have to have another surgery related to the surgery that you had, or go to the emergency room within 30 days of surgery, and the quality of your recovery 1 day after surgery.

If for any reason your surgeon decides that your laparoscopic procedure will be converted to an open procedure you will no longer be part of the study. You will be notified of this once you wake up from anesthesia.

How Long Will I Be in the Study?

You will be involved in the study from the time you sign the consent form through 30 days after surgery.

What Other Choices Do I Have?

You do not have to take part in this study to receive anesthesia for your surgery. If you decide not to participate in this study, you will receive routine anesthesia care during your surgery.

Are There Benefits to Taking Part in the Study?

This study may allow doctors to learn more about techniques to reduce the use of opioids which may improve recovery after hiatal hernia surgery. Information obtained from this study may be helpful to others having the same type of surgery in the future.

What Side Effects or Risks Can I Expect?

The anesthesia drugs used in this study might have undesired effects. These effects can be mild or very serious and even life threatening. However, all drugs used in this study are approved by the Food and Drug Administration (FDA) for anesthesia care. While the OSA is not the usual treatment, there is limited evidence that using the OSA or OBA protocol will provide different levels of risk to your procedure, other than the risks discussed by your surgeon and anesthesia team.

Opioid Based Anesthesia Risks:

Opioid Adverse Effects:

>10%:

- Nausea
- Vomiting

1-10%:

- Addiction
- Inability to go to the bathroom
- Confusion and Hallucinations
- Difficulty Breathing
- Skin Rash
- Low blood pressure
- Low heart rate
- Abnormal liver tests
- Longer recovery time from anesthesia

Opioid Sparing Anesthesia Risks (dexmedetomidine and ketamine):

Dexmedetomidine Adverse Effects:

>10%:

- Hypotension (25-28%) (Low blood pressure)
- Hypertension (12-16%) (Increased blood pressure)
- Nausea (9-11%) (Uneasiness in the stomach)

1-10%:

- Bradycardia (5-7%) (Slow heart rate)
- Pyrexia (4-5%)
- Atrial fibrillation (4%) (Abnormal heart rhythm)
- Dry mouth (3-4%)
- Vomiting (3-4%)
- Hypoxia (2-4%) (Reduced oxygen)
- Hypovolemia (3%) (Reduced blood or fluid)
- Atelectasis (3%) (Collapsed lung)
- Tachycardia (2-3%) (Increased heart rate)
- Post-procedural hemorrhage (2-3%) (Bleeding after your procedure)
- Anemia (2-3%) (Reduced red blood cells)
- Agitation (2%)
- Hyperthermia (2%) (Increased temperature)
- Pain (2%)
- Hyperglycemia (2%) (Increased sugar level)
- Chills or rigors (2%)
- Oliguria (2%) (Production of small amounts of urine)
- Thirst (2%)
- Acidosis (1-2%) (Blood is acidic)
- Pleural effusion (1-2%) (Buildup of fluid in the chest)
- Pulmonary edema (1%) (Fluid in the lungs)
- Hypocalcemia (1%) (Decreased calcium)
- Urine output decreased (1%)
- Sinus tachycardia (1%) (Normal, fast heart rate)

<1%:

- Ventricular tachycardia (dangerous, abnormal heart rhythm)
- Wheezing
- Peripheral edema (fluid buildup in the arms and legs)

Ketamine Adverse Effects:

>10%: these adverse effects are typically seen more at higher doses than being used in the present study.

- Hypertension (Increased blood pressure)
- Increased Cardiac Output (Increased amount of blood pumped per minute)
- Increased Intracranial Pressure (Increased pressure on the brain)
- Tachycardia (Fast heart rate)
- Tonic-clonic movements (Rigidity followed by violent shaking of muscles)
- Visual hallucinations (Seeing things that are not there)
- Vivid Dreams (Remembering dreams as if they were real)

1-10%:

- Bradycardia (Slow heart rate)
- Diplopia (Double vision)
- Hypotension (Low blood pressure)
- Increased Intraocular Pressure (Increased pressure around the eye)
- Nystagmus (Repetitive, uncontrolled eye movements)

<1%:

- Anaphylaxis (Severe allergic reaction)
- Cardiac arrhythmia (Abnormal heart rhythm)
- Depressed cough reflex (Inability to cough)
- Fasciculation (Involuntary twitch of an individual muscle)
- Hypersalivation (Increased production of saliva in the mouth)
- Increased metabolic rate (Increased speed of breakdown of food)
- Hypertonia (Muscles are too stiff)
- Laryngospasm (Seizing of the vocal cords)
- Apnea/Respiratory Depression (Stop/reduced breathing)

Reproductive Risks:

The drugs used in this study can affect an unborn baby and a man's sperm. If you are a person born female and of child bearing age, you will be screened prior to your surgery. Subjects who are pregnant cannot participate in this study.

Will My Medical Information Be Kept Private?

Information from this study could be published in journals or presented at meetings. If either of these happens, your name and other personal information will not be used. The researchers running this study will keep your personal information private. Your research file can also be looked at by the Endeavor Institutional Review Board, other medical personnel at Endeavor who are involved in your care, or by the Food and Drug Administration (FDA).

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 my information be used for research in the future?

Information collected from you for this research study may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information is shared. Since identifying information will be removed, you will not be asked for additional consent.

Protected Health Information (PHI)

During this research, identifiable information about your health will be collected. In the rest of this section, we refer to this information simply as “protected health information (PHI).” In general, under federal law, PHI is private. However, there are exceptions to this rule, and you should know who may be able to see, use and share your PHI for research and why they may need to do so.

Your PHI will only be used for the purposes described in this Consent Form. Your authorization for activities described in this section does not have an expiration date.

What protected health information (PHI) will be used?

- Past, present and future medical records, including information housed in the Electronic Medical Record called “Epic,” which is maintained by Endeavor Health
- Information about research procedures, including medical tests, procedures, interviews and questionnaires

Who may see, use and share my PHI and why may they need to do so?

- Endeavor research staff involved in this study
- Non-research staff within Endeavor who need this information to do their jobs (such as for treatment, payment (billing) or health care operations)
- The Endeavor IRB board that oversees the research and the Endeavor research quality improvement program
- Federal and state agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health and other US government bodies that oversee or review research)
- The sponsor(s) of this study, and the people or groups it hires to help perform this research
- Other researchers and medical centers that are part of this study and their ethics boards
- A group that oversees the data (study information) and safety of this research
- People or groups that we hire to do work for us, such as data storage companies, insurers and lawyers
- Public health and safety authorities (for example, if we learn information that could mean harm to you or others, we may need to report this, as required by law)

Some people or groups who get your PHI might not have to follow the same privacy rules that we follow. We share your PHI only when we must and we ask anyone who receives it from us to protect your privacy. However, if your information is shared outside Endeavor, we cannot promise that it will remain private.

Do I have the right to withdraw permission for the use of my PHI?

You have the right to withdraw your permission for us to use or share your PHI for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. Once permission is withdrawn, you cannot continue to take

part in this study. However, you will not be penalized or lose any benefits to which you are entitled.

Do I have access to my health information?

You have the right to see and get a copy of your PHI that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. However, to protect the study, you will not be able to see some of the study information until after the study is completed. The researchers are not required to release to you research information that is not part of your medical record.

You have the right *not* to sign this form that allows us to use and share your PHI for research; however, if you do not sign it, you cannot take part in this research study.

Will I Be Paid for Participating?

You will not be paid for being in this study.

Will There Be Additional Costs?

There is no additional cost to you from being in this research study. You will still be responsible for all costs that you would normally incur as part of routine care.

What If I Am Injured During the Study?

If you become hurt or sick because of being in this research study, you can get medical treatment at Endeavor. You or your health insurance plan will be billed. No money has been set aside to pay the costs of this treatment. You can ask for more information from the Research Institute of Endeavor.

Health insurance plans (including Medicare) may or may not cover costs of research-related injury or illness. You should check with your insurance company before deciding to participate in this research study. Costs not covered by insurance could be substantial.

Can I Withdraw from the Study?

Your participation in this research study is voluntary. If you decide not to be in this study, you will still get medical care as usual. If you decide to participate now, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits.

What Are My Rights as a Research Subject?

You may get more information about your rights from the Chairperson of the Institutional Review Board (IRB). You can also call the IRB Coordinators at 224/364-7100. These are the people you should contact about any problems or research-related injuries that happen during the research study.

By participating in this research study you do not waive any rights to which you would normally be entitled.

Will I Be Informed of New Information About the Study?

Any significant new information that may affect your participation will be given to you as soon as it becomes available.

Who Can I Call with Questions?

The study doctor and staff will answer any questions you have. If you have additional questions at any time during the study, you may contact the Principal Investigator, Dr. Steven Greenberg, at telephone: 847-570-1197.

INDIVIDUAL PROVIDING EXPLANATION:

The procedures and/or investigations described in the above paragraphs have been explained to you by:

Name of Person Explaining Study (Please PRINT)	
Signature of Person Explaining Study	
Date Study Was Explained	

CONSENT TO PARTICIPATE:

I understand that the Principal Investigator and study staff will supervise the study. I have read this consent form or have had it read to me. I understand what will happen if I enroll in this research study. I understand the possible benefits and risks of the study. I have been told about all of my treatment options. I give permission for the research study procedures described in this consent form.

I have reviewed this information with the study doctor and/or staff. I have had enough time to talk about all of my questions and concerns. I willingly consent to be a part of this study. I will receive a signed and dated copy of this Consent Form.

Subject's Name (Please PRINT)	
Subject's Signature	
Date Subject Signed	