# Influence of Anesthetic Technique on Acute and Chronic Neuropathic Pain

ClinicalTrials.gov Identifier: NCT02527083

Informed Consent Form

Document Date: 5/22/2017

| VA Department of Veterans Affairs | VA RESEARCH CONSENT FORM |
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Subject Name: _____Last 4 SSN:_____ Date: _____

Title of Study: Influence of Anesthetic Technique on Acute and Chronic Pain

Principal Investigator: James W. Ibinson, MD, PhD VAMC: Pittsburgh (646)

LAY TITLE: Influence of Anesthetic Technique on Acute and Chronic Pain

STUDY CONTACT INFORMATION:
If you have a general question about this research study, or if you have any concerns or complaints related to this research study, you may call Dr. James Ibinson at 412-360-1484 or any of the investigators listed below.

If you experience any illness, injury or other medical problem that you feel may be related to this study, please call Dr. James Ibinson, Principal Investigator, at 412-360-1484 during normal business hours. You may also contact either of the Co-investigators listed below. After-hours or on weekends call 1-866-785-9015 and tell the operator that you are a research subject from the Pittsburgh VA and need to speak with Dr. James Ibinson. Then give the operator a phone number where you can be reached. The operator will get in touch with Dr. Ibinson or another person listed below who will call you back. In the case of a medical emergency contact your local emergency medical service or go to your local emergency room.

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STUDY SPONSOR: None

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PURPOSE OF THE RESEARCH STUDY: The purpose of this research study is to determine the effects of different anesthetic techniques on short-term and long-term pain after surgery. You might not have long term pain now, but after surgery with anesthesia, some persons may begin to experience long term pain, which may be related to the type of anesthetic used. There are a number of anesthesia regimens that are commonly used in surgery but we don't know if one is better than another in preventing pain after surgery. These anesthetic techniques are the "standard of care", meaning that they are approved medications found to be safe and effective. They are used on patients undergoing various surgery types requiring general anesthesia. You will be randomly assigned to one of three anesthetic techniques: one of two techniques where anesthesia is primarily maintained by a drug called propofol through an IV, or a technique where an inhaled drug called sevoflurane is the primary medication. No matter which group you are in, you will receive the standard and appropriate dose for your age, size, and type of surgery throughout the procedure. Multiple surveys about pain type, severity, and frequency will be given to you at various time points before and after the surgery to measure your pain level. This research will have no effect on the amount of pain medication you receive at any point during or after the procedure.

You are being asked to participate in this research study because you are a patient who will undergo hernia repair surgery at the VA of Pittsburgh. The study is being performed on a total of 48 individuals.

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 Website will include a summary of the results. You can search this Web site at any time.

DESCRIPTION OF THE RESEARCH STUDY:

*Study Procedures*

If you qualify to take part in this research study, you will undergo the experimental procedures listed below.

1. On the day of surgery, you will be assigned by chance (like flipping a coin) to one of the three groups. All three groups use propofol and other medications to start anesthesia and relax muscles. The differences will be the main anesthesia medicines used during the surgery. The main medications in the three groups are:
   a. Propofol and remifentanil (intravenous)
   b. Propofol and ketamine (intravenous)
   c. Sevoflurane (inhaled)

2. You will be asked questions about other medical conditions which may influence pain scores. You will also be asked about any type of prescription or non-prescription pain drugs including how much and how long you have been taking them, and the reason that you need them (like back or leg pain).
3. You will also be asked to complete four questionnaires: the Numerical Rating Scale, the Leeds Assessment of Neurologic Symptoms & Signs, the Short Form McGill Pain Questionnaire, and the Pain Quality Assessment Scale. These questionnaires will be used to determine a baseline level of pain at the site of the hernia prior to undergoing surgical repair. These questionnaires will take approximately 15 minutes to complete.
4. During your surgery, we will keep track of the medications and amounts that you were given.
5. Shortly after your surgery, you will be asked to complete four questionnaires again.

*Follow-up Phone Calls*
We will then contact you by phone approximately 24 hours, 1 month, 3 months, 6 months, and 12 months after your surgery to repeat the four surveys. A return visit to the University Drive Division of the VA Pittsburgh Healthcare System is not required. It is estimated that each phone call will take approximately 10 minutes to complete. Also note that if you are still in the hospital the day after the surgery, we may simply try to meet you in your hospital room instead of calling. As part of the research, we will ask you about the pain medications you are currently using during each phone call, so we ask you to keep track of the pain medicines you use.

If we are unable to reach you via telephone, we will send you a paper format of the surveys with a self-addressed stamped envelope at each time period. If you have any questions about the surveys, or need any questions clarified, you may ask us at any time (using the phone numbers on the cover page).

*End of Study Procedures*
No further participation is needed after the 12-month post-operation surveys are completed.

RISKS AND BENEFITS:

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Anesthesia Medications and Procedures:
The anesthesia regimens are considered standard of care. The medications you receive may be different than you would have received if you do not participate in the study and the side effects may be different. The most common side effects (1-10% of people) for each of the three groups are:

a. Propofol and remifentanil (intravenous) – low breathing rate, low blood pressure, burning/stinging pain on injection, rash, dizziness, agitation, confusion, nausea/vomiting, low heart rate.
b. Propofol and ketamine (intravenous) – low breathing rate, low blood pressure, burning/stinging pain on injection, rash, dizziness, agitation, confusion, high breathing rate, high heart rate, high blood pressure, rapid eye movements.
c. Sevoflurane (inhaled) – low blood pressure, low heart rate, tiredness, agitation, confusion, nausea/vomiting, cough.

You may also experience some side effects related to the medications and/or treatments you receive that are not part of the research, but are considered standard of care for your condition. A description of these risks and side effects should have been provided to you by your physician. If you have not received information regarding these side effects, please contact your physician.

Study Surveys: This study will involve answering questions about any pain that you are feeling; and questionnaires do involve some inconvenience. The inconvenience includes the process of answering questions over the next year.

Because there may be other risks associated with participating in multiple research studies, you must tell the research staff about any other studies you are currently participating in, both within and outside of the VA.

Confidentiality: Every effort will be made to make sure that the information about you obtained from this study will be kept strictly confidential. As private information is collected about you as part of this study, there is a risk to your privacy and confidentiality. The research staff will take every precaution to protect your identity and the confidentiality of the information collected about you. You will not be identified by name in any publication of research results. All paper-copy records detailing any patient involvement in this research study will be stored in a locked file cabinet in the VAPHS Anesthesia Service Office. All computerized records detailing any

patient involvement in this research study will be secured in government-approved VAPHS computers. On all research paperwork, each patient's identity will be indicated by a case number. Information tying each patient with their case number will only be accessible to the investigators.

In addition, Federal agencies, including but not limited to, the Food and Drug Administration (FDA), Office of Human Research Protections (OHRP), VA's Office of Research Oversight (ORO) and the VA Office of the Inspector General (OIG) may have access to your research records. The Food and Drug Administration (FDA) may also choose to inspect research records, which may include your individual medical records, if this research is FDA-regulated. Research records, just like hospital medical records, may be released or disclosed pursuant to applicable federal and state law as well as to federal and state agencies that are responsible for oversight of medical research. Additionally, any medical information may be shared with your healthcare provider(s) with your consent, and possibly without your consent if permissible under federal laws and regulations. Finally, you consent to the publication of the study results so long as the information about you is anonymous and/or disguised so that your identity will not be disclosed.

You will not directly benefit from participating in this study. Your participation may help medical research determine ways to decrease short and long-term pain after surgery and understand the factors leading to the development of chronic pain.

ALTERNATIVES TO PARTICIPATION:
You have the alternative of not participating in this research study. If you choose not to participate, all standard anesthesia choices are available outside of the study.

NEW FINDINGS: You will be informed of any significant new findings during the course of the study, which may affect your willingness to continue to participate.

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INVESTIGATOR INITIATED WITHDRAWAL: The investigator(s) may stop your participation in this study without your consent for reasons such as: it will be in your best interest; you do not follow the study plan; or you experience a study-related injury. Your participation may also be terminated before the 12-month follow-up period if sufficient data has already been collected at earlier time points.

VOLUNTARY PARTICIPATION/RIGHT TO WITHDRAW: Your participation in this study is voluntary. You do not have to take part in this study, and your refusal to participate will involve no penalty or loss of rights to which you are entitled. You may withdraw from this study at any time without penalty or loss of VA or other benefits to which you are entitled.

Your doctor is also involved as an investigator in this research study. As both your doctor and a research investigator, s/he is interested both in your medical care and the conduct of this research study. You are under no obligation to participate in this or any other research study offered by your doctor. Before you agree to participate in this research study, or at any time during your participation in this study, you may discuss your care with another doctor who is not associated with this research study.

MEDICAL TREATMENT: In the event that you sustain injury or illness as a result of your participation in this VA approved research study, conducted under the supervision of one or more VA employees, all medical treatment (emergent as well as medical treatment beyond necessary emergent care) will be provided by the VA. Except in limited circumstances, the necessary medical care must be provided in VA medical facilities.

However, if such injury or illness occurred as a result of your failure to follow the instructions for this study, you may not be eligible for free care unless you have independent eligibility for such care under Federal Law.

FINANCIAL COMPENSATION: If you sustain an injury or illness as a result of participating in this research study, you may be eligible to receive monetary compensation for your damages pursuant to applicable federal law. If you believe that you are injured as a result of participation in this study, please contact the Principal Investigator. If compensation is available the Principal Investigator will provide you with an explanation as to what that compensation consists of, or where you can obtain further information regarding it.

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COST AND PAYMENTS: You or your insurance will not be charged for any costs related to the research. However if you are receiving medical care and services from the VA that are not part of this study, and you are a veteran described in federal regulations as a "category 7" veteran, you may be required to make co-payments for the care and services that are not required as part of this research study. There is no payment to you associated with this study.

RECORD RETENTION: Your research records will be retained in accordance with the Veterans Health Administration (VHA) Records Control Schedule, or longer, if required by other Federal regulations.

RESEARCH SUBJECTS' RIGHTS: You have read or have had read to you all of the above and any applicable consent addenda. Dr. James Ibinson or his/her authorized representative has explained the study and any optional study components to you and answered all of your questions. The risks, discomforts, and possible benefits of this research study, as well as alternative treatment choices, have been explained to you.

A description of the study has been provided to you, including an explanation of what this study is about, why it is being done, and the procedures involved. You have the right to ask questions related to this study or your participation in this study at any time. You should be giving your consent only under conditions in which you (or the person representing you) have sufficient opportunity to carefully consider whether or not to participate in this study. Your consent should not be given under conditions that pressure you or try to influence your decision in any way.

Your rights as a research subject have been explained to you, and you voluntarily consent to participate in this research study. You understand that these Research Subjects' Rights also apply to any optional study components to which you have agreed to participate. You will receive a copy of this signed consent form.

If you have any questions about your rights as a participant in this study, or wish to speak more about the study with someone not associated with the research study, you can call the Associate Chief of Staff for Research and Development at (412) 360-2394

As long as the study is renewed as required by the IRB, your signature on this document is valid for the duration of the entire research study. Should any changes occur during the course of the study that may affect your willingness to participate, you will be notified.

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***By signing this form, you agree to participate in this research study.***

| _____ | _____ | _____ |
|---|---|---|
| Subject's Signature | Date | Time |
| _____ | _____ | _____ |
| Investigator/Person Obtaining Consent* | Researcher (Print) | Date |

**Version Date: 5/5/17**