Does a Ketamine Infusion Decrease Post Operative Narcotics

NCT03001843

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UF | Institutional Review Board
UNIVERSITY of FLORIDA

INFORMED CONSENT FORM
to Participate in Research, and

AUTHORIZATION
to Collect, Use, and Disclose Protected Health Information (PHI)

INTRODUCTION

Name of person seeking your consent:_____

Place of employment & position: _____

Please read this form, which describes the study in some detail. A member of the research team will describe this study to you and answer all of your questions. Your participation is entirely voluntary. If you choose to participate you can change your mind at any time and withdraw from the study. You will not be penalized in any way or lose any benefits to which you would otherwise be entitled if you choose not to participate in this study or to withdraw. If you have questions about your rights as a research subject, please call the University of Florida Institutional Review Board (IRB) office at (352) 273-9600.

GENERAL INFORMATION ABOUT THIS STUDY

1. Name of Participant ("Study Subject")

_____

2. What is the Title of this research study?

Does a Ketamine Infusion Decrease Post Operative Narcotics

3. Who do you call if you have questions about this research study?

Principal Investigator: David Smyth CRNA (352) 642-5859 24 hours a day

Co-Investigatort: Josh Sappenfield, M.D., office: 352-273-6567

4. Who is paying for this research study?

The sponsor of this study is the University of Florida.

5. Why is this research study being done?

This research is being done to see if medication we administer in the operating room during weight loss surgery can help to decrease the amount of narcotics patients need after surgery while still keeping their pain adequately controlled. You are being invited to participate in this study as you are scheduled to undergo a weight loss surgery.

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.

WHAT CAN YOU EXPECT IF YOU PARTICIPATE IN THIS STUDY?

6. What will be done as part of your normal clinical care (even if you did not participate in this research study)?

You will receive a laparoscopic gastric bypass and all of the usual medical care associated with that procedure.

7. What will be done only because you are in this research study?

The type of pain medication given during the operation will be controlled by the study guidelines. You will be randomly assigned – much like the flip of a coin - to one of two groups; half of the participants will receive a ketamine infusion, the other half will be receiving narcotic pain medications (what is usually given during surgery) to control your pain; you will not know which medication you receive during the operation. Both types of medication are in common use and FDA approved. After the surgery you will be given pain medications to keep your pain levels under control. We will be collecting data on how you rate your pain as well as how much medication is required to keep you comfortable.

If you have any questions now or at any time during the study, please contact one of the research team members listed in question 3 of this form.

8. How long will you be in this research study?

This study will follow you during your surgery and for 48 hours after surgery.

9. How many people are expected to take part in this research study?

We will be following up to 58 participants in this study.

WHAT ARE THE RISKS AND BENEFITS OF THIS STUDY AND WHAT ARE YOUR OPTIONS?

10. What are the possible discomforts and risks from taking part in this research study?

The major side effect from Ketamine is an "emergence reaction" and can include a dreamlike state and vivid dreams, possibly some nightmares. Some of this may be avoided by small dose of relaxing mediation regularly given to surgical patients before going of the operating room. You will receive the relaxing medication, regardless of the group you will be assigned to. You will be monitored for this emergence reaction and treated as indicated as part of your stay in the recovery unit. If you receive narcotic medications only you are not expected to have an emergence reaction, but may have a slightly greater chance of postoperative nausea and it may take longer for your bowels to move.

11a. What are the potential benefits to you for taking part in this research study?

You may or may not benefit from participation in this study, because we do not know whether one approach is better than the other.

11b. How could others possibly benefit from this study?

If this approach can decrease the need for narcotic medications after gastric bypass surgery while keeping pain levels adequate, we can recommend this anesthetic approach for patients having gastric bypass surgery.

11c. How could the researchers benefit from this study?

In general, presenting research results helps the career of a scientist. Therefore, the Principal Investigator listed in question 3 of this form may benefit if the results of this study are presented at scientific meetings or in scientific journals.

12. What other choices do you have if you do not want to be in this study?

You do not have to participate in this study. It will not negatively affect your anesthesia care if you decide not to participate. You will receive anesthesia and pain medications for your surgery whether you participate or not.

13a. Can you withdraw from this study?

You are free to withdraw your consent and to stop participating in this study at any time. If you do withdraw your consent, you will not be penalized in any way and you will not lose any benefits to which you are entitled.

If you decide to withdraw your consent to participate in this study for any reason, please contact one of the research team members listed in question 3 of this form. They will tell you how to stop your participation safely.

If you have any questions regarding your rights as a research subject, please call the Institutional Review Board (IRB) office at (352) 273-9600.

13b. If you withdraw, can information about you still be used and/or collected?

If you withdraw from the study no new information will be collected for study purposes. You will still be asked to rate your pain and your medications will be part of your normal medical record as this data is normally collected whether you are involved in the study or not, it will just not be reviewed by the study staff.

13c. Can the Principal Investigator withdraw you from this study?

You may be withdrawn from the study without your consent for the following reasons:

- The study doctor considers it advisable for a clinical reason
- If it is in your best interest
- You no longer meet the criteria for the study

WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

14. If you choose to take part in this research study, will it cost you anything?

Study Drugs

The cost the drugs used in this study will be billed to you or your insurance company in the usual manner. You will be responsible for paying any deductible, co-insurance, or co-payments for these services, and for any non-covered or out-of-network services.

Study Services

The Sponsor will pay for the following study-required activities at no cost to you:
1. Review of your medical history.
2. Data collection from your medical chart.

If you receive a bill for these services, please contact David Smyth at (352) 642-5859.

Items/Services Not Paid for by the Sponsor
All medical services you receive would have been provided to you even if you were not in this study. These services will be billed to you or your insurance company in the usual manner. You will be responsible for paying any deductible, co-insurance, or co-payments for these services, and for any non-covered or out-of-network services.

15. Will you be paid for taking part in this study?

No.

16. What if you are injured because of the study?

Since this is a data collection study, there is a very low risk of study-related injury. However, if you are injured as a direct result of your participation in this study, only the professional services that you receive from any University of Florida Health Science Center healthcare provider will be provided without charge. These healthcare providers include physicians, physician assistants, nurse practitioners, dentists or psychologists. Any other expenses, including Shands hospital expenses, will be billed to you or your insurance provider.

You will be responsible for any deductible, co-insurance, or co-payments. Some insurance companies may not cover costs associated with research studies or research-related injuries. Please contact your insurance company for additional information.

The Principal Investigator will determine whether your injury is related to your participation in this study.

No additional compensation is routinely offered. The Principal Investigator and others involved in this study may be University of Florida employees. As employees of the University, they are protected under state law, which limits financial recovery for negligence.

Please contact one of the research team members listed in question 3 of this form if you experience an injury or have questions about any discomforts that you experience while participating in this study.

17. How will your health information be collected, used and shared?

If you agree to participate in this study, the Principal Investigator will create, collect, and use private information about you and your health. This information is called protected health information or PHI. In order to do this, the Principal Investigator needs your authorization. The following section describes what PHI will be collected, used and shared, how it will be collected, used, and shared, who will collect, use or share it, who will have access to it, how it will be secured, and what your rights are to revoke this authorization.

Your protected health information may be collected, used, and shared with others to determine if you can participate in the study, and then as part of your participation in the study. This information can be gathered from you or your past, current or future health records, from procedures such as physical examinations, x-rays, blood or urine tests or from other procedures or tests. This information will be created by participating in study procedures. More specifically, the following information may be collected, used, and shared with others:

- Information about your health history
- Your reported pain levels and amount of medications taken to treat pain.
- Your name, gender, date of birth, medical record number, dates of you pre-operative clinic visit and surgery
- Your anesthesiology records about this surgery

This information will be stored in locked filing cabinets or on computer servers with secure passwords, or encrypted electronic storage devices.

Some of the information collected could be included in a "limited data set" to be used for other research purposes. If so, the limited data set will only include information that does not directly identify you. For example, the limited data set cannot include your name, address, telephone number, social security number, photographs, or other codes that link you to the information in the limited data set. If limited data sets are created and used, agreements between the parties creating and receiving the limited data set are required in order to protect your identity and confidentiality and privacy.

18. For what study-related purposes will your protected health information be collected, used, and shared with others?

Your PHI may be collected, used, and shared with others to make sure you can participate in the research, through your participation in the research, and to evaluate the results of the research study. More specifically, your PHI may be collected, used, and shared with others for the following study-related purpose(s):

To determine if administration of the study medication during surgery can help decrease post-operative narcotic needs while providing satisfactory pain control.

Once this information is collected, it becomes part of the research record for this study.

19. Who will be allowed to collect, use, and share your protected health information?

Only certain people have the legal right to collect, use and share your research records, and they will protect the privacy and security of these records to the extent the law allows. These people include:

- the study Principal Investigator (listed in question 3 of this form) and research staff associated with this project.
- other professionals at the University of Florida or Shands Hospital that provide study-related treatment or procedures.
- the University of Florida Institutional Review Board (IRB; an IRB is a group of people who are responsible for looking after the rights and welfare of people taking part in research).

20. Once collected or used, who may your protected health information be shared with?

Your PHI may be shared with:

- The study sponsor (listed in Question 4 of this form).
- United States governmental agencies who are responsible for overseeing research, such as the Food and Drug Administration, the Department of Health and Human Services, and the Office of Human Research Protections.
- Government agencies who are responsible for overseeing public health concerns such as the Centers for Disease Control and federal, state and local health departments.

Otherwise, your research records will not be released without your permission unless required by law or a court order. It is possible that once this information is shared with authorized persons, it could be shared by the persons or agencies who receive it and it would no longer be protected by the federal medical privacy law.

21. If you agree to take part in this research study, how long will your protected health information be used and shared with others?

Your PHI will be used and shared with others for 6 years after the study closes.

You are not required to sign this consent and authorization or allow researchers to collect, use and share your PHI. Your refusal to sign will not affect your treatment, payment, enrollment, or eligibility for any benefits outside this research study. However, you cannot participate in this research unless you allow the collection, use and sharing of your protected health information by signing this consent and authorization.

You have the right to review and copy your protected health information. However, we can make this available only after the study is finished.

You can revoke your authorization at any time before, during, or after your participation in this study. If you revoke it, no new information will be collected about you. However, information that was already collected may still be used and shared with others if the researchers have relied on it to complete the research. You can revoke your authorization by giving a written request with your signature on it to the Principal Investigator.

SIGNATURES

As an investigator or the investigator's representative, I have explained to the participant the purpose, the procedures, the possible benefits, and the risks of this research study; the alternative to being in the study; and how the participant's protected health information will be collected, used, and shared with others:

Signature of Person Obtaining Consent and Authorization	Date

You have been informed about this study's purpose, procedures, possible benefits, and risks; the alternatives to being in the study; and how your protected health information will be collected, used and shared with others. You have received a copy of this Form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask questions at any time.

You voluntarily agree to participate in this study. You hereby authorize the collection, use and sharing of your protected health information as described in sections 17-21 above. By signing this form, you are not waiving any of your legal rights.

Signature of Person Consenting and Authorizing	Date