

**Effect of intraoperative and post-operative opioids on persistent  
opioid use in the surgical patient**

**NCT#: Not Assigned**

## **CONSENT TO BE IN A RESEARCH STUDY**

**TITLE:** Effect of intraoperative and post-operative opioids on persistent opioid use in the surgical patient

**SITE(S):** Tampa General Hospital  
1 Tampa General Circle  
Tampa, Florida 33606  
United States

**INVESTIGATOR:** Enrico Camporesi, MD  
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Tampa, Florida 33606  
United States

**STUDY-RELATED  
PHONE NUMBER(S):** PI - Enrico Camporesi, MD: (813) 600-9094

## **INTRODUCTION**

The anesthesia group at Tampa General Hospital (TGH) is staffed by Gulf-to-Bay Anesthesiology Associates, LLC, a clinical group. We are conducting a clinical study (a type of research study). This consent form provides information on the procedures and risks involved in this clinical study. Please read this form carefully so that you can decide if you want to take part in the study. Should you decide to join this study, you can stop at any time.

You may want to talk to your family, friends, or primary care doctor before making your decision.

Please ask the study doctor about any questions that you may have about this study. If you do not take part in this study it will not affect your continued medical treatment.

## **PURPOSE OF THE STUDY**

Prior to your surgery, you will be given anesthesia. Anesthesia is an important part of your care during surgery, and its effects can last well after surgery. The types of medications used have an impact on your recovery in the PACU and potentially your pain after discharge.

Opioid use as part of a surgical anesthetic is common practice; more recently however, clinically approved methods of anesthesia that remove all opioid use have been developed. While both of these methods of anesthesia are clinically approved and deemed safe and effective for pain management, few studies directly compare the risks and benefits of the two methods.

You are being asked to be a part of the study because you will be having a particular type of surgery where either type of anesthesia, opioid or opioid-free is an accepted practice, and depending on the practices of your surgeon, anesthesiologist, and/or certified registered nurse anesthetist you could receive either of these methods of anesthesia. You will be given all required medicines and treatment regardless of whether you decide to participate in the study or not.

## **DESCRIPTION OF THE STUDY**

This study compares the risks and benefits of two types of anesthesia, one with opioids and one without opioids. Patients will be assigned to one of these types of anesthesia at random in a 1:1 ratio. Prior to and during the surgery they will be given the type of anesthesia they are assigned. Patients will be monitored after their surgery while they recover in the post-anesthesia care unit. Upon discharge patients will fill-out and submit weekly electronic surveys regarding their opioid usage and pain. These weekly surveys will be filled-out and submitted by phone. Electronic surveys will be given every week for 12 months or until the patient stops using their opioid prescription as confirmed by the study PI.

## **HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?**

A total of 100 people at Tampa General Hospital will participate in this study. 50 will receive opioid anesthesia. 50 will receive opioid free anesthesia.

## **HOW LONG WILL I BE IN THIS STUDY?**

If you meet the conditions to be a part of this study and agree to participate, you will be a part of the study for the entire length of your surgical procedure, for the length of your stay at the hospital, and up to 12 months after your hospital discharge, depending on your opioid usage after discharge. Stopping your current post-surgery opioid prescription will mark your completion of the study and you will no longer be prompted to fill-out weekly surveys. You can leave the study at anytime you want without losing any of your rights to current or future medical care at the hospital. If you decide to leave the study, we hope you will talk to the study staff to learn about any possible health or safety consequences.

## **WHAT WILL HAPPEN TO ME?**

This study looks at both the immediate and long-term effects of opioid and opioid-free anesthesia. After signing this consent form you will be randomly assigned to one of two study groups:

1. Opioid Anesthesia - the patient will receive opioids as part of their anesthesia regiment
2. Opioid-free Anesthesia - the patient will receive no opioids as part of their anesthesia regiment

Both of the listed anesthesia regimens are approved methods of anesthesia at TGH; neither regimen deviates from approved standard of care. You will not know to which group they are assigned.

Prior to surgery, you will be given two surveys:

- A) Brief Pain Inventory – 9 question survey that assesses your current level of pain

B) SOAPP-R – 24 question survey that assesses opioid use and potential for substance abuse

On the day of surgery you will be given anesthesia according to your group assignment. Following your surgery, you will be monitored in the post anesthesia care unit. Where your post-operative pain and nausea will be assessed every 15 minutes until discharged to floorstay. If your pain is higher than the hospital recommended threshold you will be given a standardized rescue dose of IV dilaudid, 0.4mg per dose up to a max dose of 2mg every 2 hours or until your pain has subsided. Your post-operative PACU narcotic consumption will be recorded.

Post-operative nausea and vomiting will also be assessed every 15 minutes until PACU discharge. Nausea will be treated with medications as needed.

As this is also a long-term follow-up study, you will be asked to electronically submit weekly surveys on your pain, satisfaction of care, and pain medication use. You will receive and fill out these surveys via your mobile phone. This will require you to download and give permissions to the REDCap phone application. The REDCap app will send you weekly notifications to remind you to fill out your surveys.

## **CAN ANYTHING HAPPEN TO ME? WHAT ARE THE RISKS?**

Both of the listed anesthesia regimens are approved methods of anesthesia at TGH; neither regimen deviates from approved standard of care. Thus, there are no risks associated with taking part in this study.

## **WILL I BENEFIT FROM THIS RESEARCH?**

You may not receive any medical benefit; we do not know whether removing opioids from anesthesia will result in fewer side effects such as nausea and vomiting or result in curbed opioid use upon discharge from the hospital. That is why we are doing this study.

Although you may not receive any benefit from participating in this study, medical science and future patients may benefit from your participation.

## **WILL I GET PAID?**

You will receive \$50 compensation upon completion of your final survey if every prior survey has also been properly filled out and submitted

## **WILL IT COST ANYTHING TO BE IN THE STUDY?**

It will not cost you anything to be part of the study. All other charges will be the responsibility of you or your insurance company because you would receive these as part of your regular medical care. These are costs that are considered medically reasonable and necessary and would be part of the care you

would receive if you did not take part in this study. However, you may want to check with your insurer to see if they will cover these costs.

## **WHAT OTHER TREATMENT CHOICES ARE THERE?**

If you choose not to take part in this study you will not be assigned an anesthesia group. Your doctor will still do his/her best to make sure that you get all of the normal care that he/she gives to surgical patients which may involve opioid or opioid-free anesthesia. Your choice not to be a part of the study will not be written in your medical records.

## **WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?**

Taking part in this study is voluntary. You may decide not to take part or you may leave the study at any time. Not taking part or leaving the study will not lead to any penalty or loss of the benefits that you should normally have. If you decide to stop being a part of the study, we hope you will talk to your study doctor or study staff first to learn about any possible health or safety consequences.

However, your study doctor, your local institution and the sponsor of this study, have the right to stop you from being a part of the study, or cancel the study, without your consent at any time for any of the following reasons:

- if it is in your best interest;
- you do not consent to continue the study after being told of changes in the research that may affect you;
- or for any other reason

## **NEW FINDINGS**

You will be given any new information we learn about that might change your choice to keep being a part of the study.

## **WHAT HAPPENS IF I GET HURT IN THE STUDY?**

In the event you suffer an injury or illness as a result of participating in this research study, please be aware that immediate, short-term medical treatment for the injuries or illness will be available to you:

If you need emergency care:

- Go to your nearest hospital or emergency room right away. Call 911 for help. It is important that you tell the doctors at the hospital or emergency room that you are participating in a research study. If possible, take a copy of this consent form with you when you go.
- Call the study doctors as soon as you can. They will need to know that you are hurt or ill. Call Dr. Enrico M. Camporesi at 813-600-9094 or the research coordinator, Garrett Enten, at 954-319-5451.

If you do NOT need emergency care:

- Go to your regular doctor. It is important that you tell your regular doctor that you are participating in a research study. If possible, take a copy of this consent form with you when you go.

This medical treatment is not free of charge. Any treatment required for a research-related injury will be billed to you or your insurer in the ordinary manner. The cost of the medical treatment will be billed to you to the extent not covered by your insurance company or government program. No other compensation will be offered. You are not giving up any legal rights by signing this form.

Processes and procedures regarding human research are in place to help prevent any injuries during the course of studies. Should you believe, however, that you have been hurt or if you get sick because of something that is done during the study, you should call Dr. Enrico M. Camporesi at 813-600-9094 immediately.

## **ADULT TAMPA GENERAL HOSPITAL INJURY STATEMENT**

In the event you suffer an injury or illness as a result of participating in this research study, please be aware that immediate, short-term medical treatment for the injuries or illness will be available to you from Tampa General Hospital. The cost of the medical treatment will be billed to you to the extent not covered by your insurance company or government program. No other compensation will be offered. You are not giving up any legal rights by signing this form. If you believe you have experienced a reaction to the study drug or have been injured as a result of research procedures performed at Tampa General Hospital, please contact the Department of Risk Management at (813) 844-7666.

## **WILL THE HOSPITAL, STUDY DOCTOR, OR COMPANY BENEFIT FROM THIS STUDY?**

No, the researchers do not hold a direct financial interest in a sponsor or products being studied.

## **AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION (HIPAA LANGUAGE)**

The federal privacy regulations of the Health Insurance Portability & Accountability Act (HIPAA) protect your identifiable health information. By signing this form, you are permitting Gulf-to-Bay Anesthesiology Associates, LLC (the Sponsor) to use your health information for research purposes. You are also allowing us to share your health information with individuals and organizations other than the Sponsor who are also involved in the research and listed below.

In addition, the following groups of people may also be able to see your health information and may use that information to conduct this research:

- The medical staff that takes care of you and those who are part of this research study;
- The research site for this study, Tampa General Hospital;
- Any laboratories, pharmacies, or others who are part of the approved plan for this study;
- All designated review committees such as Data and Safety Monitoring Board, Tampa General Hospital Feasibility Committee/Office of Clinical Research

- Data Safety Monitoring Boards or others who monitor the data and safety of the study
- There may be other people and/or organizations who may be given access to your personal health information, including Tampa General Hospital;
- Federal offices such as the Food and Drug Administration (FDA) and Health Canada that protect research subjects like you
- Individuals at the University of South Florida Institutional Review Board
- The study doctor and the team of researchers

Anyone listed above may use consultants in this research study, and may share your information with them. If you have questions about who they are, you should ask the study team. Individuals who receive your health information for this research study may not be required by the HIPAA Privacy Rule to protect it and may share your information with others without your permission. They can only do so if permitted by law. If your information is shared, it may no longer be protected by the HIPAA Privacy Rule.

By signing this form, you are giving your permission to use and/or share your health information as described in this document. As part of this research, the Sponsor and Tampa General Hospital may collect, use, and share the following information:

- Your research record
- All of your past, current or future medical and other health records held by the Sponsor, Tampa General Hospital, other healthcare providers or any other site affiliated with this study as they relate to this research project. This may include, but is not limited to records related to HIV/AIDS, mental health, substance abuse, and/or genetic information.

By signing this form, you are permitting the Sponsor and Tampa General Hospital to receive, use, and share personal health information collected about you for research purposes within Tampa General Hospital health care system. You are also allowing Tampa General Hospital to share your personal health information with other individuals or organizations who are also involved in this research.

This authorization will never expire unless and until you revoke it.

## **VOLUNTARY PARTICIPATION/RIGHT TO WITHDRAW FROM THE STUDY**

When you sign this consent and authorization form, you authorize or give permission for the use of your health information as described in the consent form. You can revoke or take away your authorization to use and disclose your health information at any time. You do this by sending a written notice to the investigator in charge of the study at the following address:

Principal Investigator: Dr. Enrico M. Camporesi  
 For IRB Study # Pro00032413  
 1 Tampa General Circle, Suite A-327  
 Tampa, FL 33606

If you withdraw your authorization, you will not be able to be in this study. If you withdraw your authorization, no new health information that identifies you will be gathered after that date. Your health information that has already been gathered may still be used and disclosed to others. This would



be done if it were necessary for the research to be reliable. You will not have access to your health information that is included in the research study records until the end of the study.

## **EMERGENCY AND IRB CONTACT**

You have the right to ask questions about the known and unknown risks of this study at any time.

The study doctor will be available and on-call during the whole study. Please call the study doctor (Dr. Enrico M. Camporesi) at 813-600-9094 if:

- You have any questions about the study
- You experience a study-related injury
- You have a medical emergency

Contact information for Tampa General Hospital, the site of this research is as follows:

Tampa General Hospital  
P.O. Box 1289  
Tampa, FL 33601  
813-844-7000

This study has been reviewed by an IRB and the FDA, meaning that the study was deemed ethically sound to conduct.

If you have any questions about your rights or related concerns as a research subject, or if you have questions, concerns, or complaints about the research, you may contact

IRB Name:	University of South Florida Institutional Review Board
Address:	12901 Bruce B. Downs Blvd, MDC35
City, State, Zip:	Tampa, FL 33612-4799
Phone:	(813) 974-2880
E-mail:	rsch-arc@usf.edu

University of South Florida Institutional Review Board is a group of people who perform independent review of research.

University of South Florida Institutional Review Board will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact University of South Florida Institutional Review Board if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

Review and approval of this study by the University of South Florida Institutional Review Board is not an endorsement of the study or its outcome.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

**If you agree to be in this study, you will be given a copy of this signed and dated 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. I have had the 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.

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Printed Name of Subject

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Signature of Subject

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Date

## **STATEMENT OF PERSON CONDUCTING INFORMED CONSENT DISCUSSION**

I have fully explained the procedures involved in this study, identifying those that are investigational, and have explained their purpose. I have asked whether or not any questions have arisen regarding the investigational procedure and have answered those questions to the best of my ability.

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Printed Name of Person Conducting Informed Consent Discussion

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Signature of Person Conducting Informed Consent Discussion

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Date