

Research Institute

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CONSENT FORM

The Effect of Methadone and Hydromorphone on the QT Interval after Anesthesia and Surgery

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Principal Investigator telephone number: 847-570-2760

Sponsor: Department of Anesthesiology

EXPLANATION OF STUDY:

Introduction: You are being asked to volunteer for this clinical research study because you are undergoing a procedure that requires a general anesthetic and will need pain medication for the procedure.

This Consent Form gives information about the study that you can talk about with your doctor and/or family. You are being given this information to help your decision. If you have any questions, you can ask the study doctor or staff.

Why is this Study Being Done?

Patients having a general anesthetic receive a number of different drugs during the course of surgery. A number of drugs used by anesthesiologists in the operating room can cause changes on the electrocardiogram (EKG) following anesthesia. In particular, about 80% of patients will demonstrate an increase in the length of the QT interval in the recovery room after surgery. The QT interval represents the time it takes the heart to contract and relax. An increase in the QT interval may predispose patients to abnormal heart rhythms, although these instances are very rare in the perioperative period.

In procedures associated with moderate-to-severe postoperative pain, a longer-acting opioid is typically administered in the operating room to provide analgesia (pain relief) as patients recover from surgery. At Evanston Hospital, both intermediate-acting (hydromorphone) and longer-acting (methadone) opioids are used in patients undergoing major surgery. Hydromorphone is more often used by anesthesiologists, but some anesthesiologists also use methadone.

At the present time, it is uncertain whether using one opioid or the other has an effect on the QT interval. Patients on long-term methadone therapy may have an increase in the QT interval, but the effect of a single dose used in the operating room is unknown. Both

methadone and hydromorphone are approved by the FDA (Food and Drug Administration) for the purposes used in this study.

The primary purpose of this study is to compare the effects of the two opioids administered in the operating room (methadone versus hydromorphone) on the EKG following surgery. In particular, the impact of these opioids on the QT interval will be measured. Standard information about your stay in the hospital will also be recorded.

This study will include a total of 140 subjects, all of who will be from NorthShore University HealthSystem (NorthShore).

What Will Happen During the Study?

If you decide to participate in this study you will be screened to see if you meet the eligibility requirements. Screening involves reviewing your medical history and results of the preoperative tests. Prior to your surgery you will be randomly assigned (like a flip of a coin) using a computerized program to one of two groups. One group will receive methadone and the other group will receive hydromorphone. You will have an equal chance of receiving either methadone or hydromorphone as part of your routine anesthesia. These drugs will be given in the same amounts that would normally be given if you weren't in the study. In all other ways subjects in the two groups will receive the same care.

Neither you nor any of the doctors or nurses will know which drug (methadone or hydromorphone) is given in the operating room. In case of an emergency, your doctor will be told which drug you received.

Prior to surgery, in the recovery room, and on the morning of the first postoperative day, a 12-lead EKG will be obtained to measure the QT interval. These EKGs will be obtained for research purposes. At this same time, you will be asked to describe your pain level and any episodes of nausea, vomiting, or itching (for research purposes). The study doctors will record standard recovery data from documents in the operating room and postoperative records (for research purposes). The study will end when you are discharged from the hospital. Additional information may be collected from the hospital record.

How Long Will I Be In the Study?

You will be in the study until you are discharged from the hospital. No follow-up procedures are needed after you are discharged.

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 standard care during your surgery. Similar doses of methadone or hydromorphone may be used if you do not take part in the study. If you do not participate, you will be asked questions about how you are feeling after surgery, but likely not as frequently as you would if you decide to take part in the study.

Are There Benefits to Taking Part in the Study?

This study may allow doctors to learn more about how opioids given in the operating room affect the QT interval following anesthesia and surgery. Information obtained from this study may be helpful to others having the same type of surgery in the future.

There is unlikely to be any direct benefit for you.

What Side Effects or Risks Can I Expect?

The opioids used in this study might have undesired effects. However, doctors do not know all the effects that may happen. Side effects may be mild or very serious. Sometimes they can be life-threatening. The study doctor will watch you carefully and will provide treatment for any effects. At the present time, it appears that the frequency of side effects from hydromorphone and methadone are similar:

Hydromorphone and Methadone Risks

<i>Common (greater than 10%)</i>	<i>Less common (1-10%)</i>	<i>Rare (less than 1%)</i>
Nausea / Vomiting	Low blood pressure	Irregular heart rhythm
Constipation	Headache	Slow breathing
Itching	Tight, rigid muscles	Apnea (stop breathing)
Sedation/sleepy	Confusion	Allergic reactions
		Pulmonary edema
		Seizures

Since methadone is a longer-acting drug, it is possible that the side effects may also be longer lasting. However, this has not been observed in previous studies.

You should not be breastfeeding an infant or toddler while on this study for at least 48 hours.

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 try to keep your personal information private. Your study related information may be looked at by other doctors in this study. Your research file can also be looked at by the NorthShore Institutional Review Board, other medical personnel at NorthShore 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.

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 NorthShore University HealthSystem
- Information about research procedures, including research office visits, medical tests, procedures, interviews and questionnaires

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

- NorthShore research staff involved in this study
- Non-research staff within NorthShore who need this information to do their jobs (such as for treatment, payment (billing) or health care operations)
- The NorthShore IRB board that oversees the research and the NorthShore 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 it hires to help perform this research
- Other researchers 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 NorthShore, 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 expected to be 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.

The Department of Anesthesiology will pay for the EKGs obtained in this investigation.

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 NorthShore. The Department of Anesthesiology will pay all costs related to the treatment of any research illness or injury. No other money has been set aside to pay any other costs you may have while in this study. You can ask for more information from the Research Institute of NorthShore.

Can I Withdraw From the Study?

Your participation in this research study is voluntary. If you decide not to be in this study, you can 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, Glenn S. Murphy, MD, at telephone: 847-570-2760.

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	