Permission to Take Part in a Human Research Study

Title of Research Study: Prospective Assessment of Perioperative Intra-articular Morphine Injection in Hip Arthroscopy on Postoperative Pain Management

Investigator: Michael Terry, MD

Supported By: This research is supported by Northwestern University.

Financial Interest Disclosure:

The following disclosure is made to give you an opportunity to decide if this relationship will affect your willingness to participate in this research study:

Your doctor, who is also responsible for this research study, is interested in both your clinical care and the conduct of this research study. You have the right to discuss this study with another person who is not part of the research team before deciding whether to participate in the research.

Why am I being asked to take part in this research study?

We are asking you to take part in this research study because you are an eligible patient having arthroscopic hip surgery.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team. Dr. Terry is in charge of this research study. You can call him at telephone 312-926-5641.

This research has been reviewed and approved by an Institutional Review Board ("IRB"). You may talk to them at (312) 503-9338 or irb@northwestern.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

Why is this research being done?

This research is being done to test the effectiveness of intra-operative (during surgery) morphine and clonidine hip injections in controlling pain shortly after arthroscopic hip surgery.

Morphine and clonidine are FDA-approved medications that are not approved for injections into the hip. For arthroscopic knee surgery, studies support intra-operative morphine and clonidine joint injections and show that clonidine in combination with morphine works better to enhance patient comfort shortly after surgery than either drug alone. Based on these studies in knee surgery, Dr. Terry regularly prescribes intra-operative morphine and clonidine hip injections in order to reduce pain

shortly after arthroscopic hip surgery. Dr. Terry's preliminary data on hip arthroscopy patients from the past year show that, on average, patients who receive a morphine/clonidine injection require less pain relief medication shortly after surgery. However, no clear scientific evidence supports or opposes the use of morphine and clonidine injections during arthroscopic hip surgery. This study, a randomized controlled trial, will assess whether intra-operative morphine and clonidine hip injections help control pain shortly after arthroscopic hip surgery.

How long will the research last?

We expect that you will be in this research study for the duration of your stay on the day of your scheduled surgery until your two week postoperative follow-up appointment.

How many people will be studied?

We expect about 100 people here will be in this research study out of 100 people in the entire study nationally.

What happens if I say "Yes, I want to be in this research"?

As a subject in this study, you will be part of a trial for the use of a morphine and clonidine joint injection during hip surgery. You will be randomly selected to either receive a standard dose of morphine and clonidine or normal saline solution through a joint injection. The normal saline will have no active drug ingredients. In either case the injection will occur at the conclusion of your surgery. The joint injection is the only change to your medical care that will occur if you should decide to participate in this study. Your pain level will be monitored and treated after surgery, and all of your pain management after surgery will follow the normal standard of care. Additionally, you will be asked to fill out a brief questionnaire before your surgery and at five different time points after your surgery.

Information about your operation such as the date and duration of surgery, side, and type of anesthesia, will be collected by Dr. Terry at the time of the hip surgery. Postoperatively, your pain scores, amount of pain medication use, and times of operating room and surgical center discharge will be recorded.

The treatment (morphine/clonidine or normal saline injection) you receive will be chosen by chance, like flipping a coin. Neither you nor the study doctor will choose what treatment you get. You will have an equal chance of being given each treatment. Neither you nor the study doctor will know what treatment you get.

No additional visits or appointments beyond what your procedure already entails are needed to participate in this study. The entirety of this study will be completed by the time of your discharge from the surgical center.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible to fill out a brief QoR-15 survey before your surgery and a short "Postoperative Pain Management" diary at 6, 18, 24, 48 hours, and 7 days after your surgery. You will also be asked to provide the medical team with pain scores and any other standard of care tasks asked by your medical provider while you are in the surgical center..

What happens if I do not want to be in this research?

You can leave the research at any time and it will not be held against you.

What happens if I say "Yes", but I change my mind later?

You can leave the research at any time it will not be held against you.

If you decide to leave the research, any data that has already been collected will remain coded but is still eligible for the study. If you decide to leave the research, contact the investigator so that the investigator can ensure removal of this coded data from the study. All medical information collected for this study will be recorded and analyzed in a database that has no personally identifying information in order to help maintain confidentiality.

Is there any way being in this study could be bad for me?

Morphine and clonidine are FDA-approved drugs that are not specifically approved for use in joint injections. Although medical literature supports the use of morphine and clonidine injections into the knee, there is no clear scientific evidence to support or oppose the use of these drugs in the hip.

No patient who has an allergy or known adverse reaction to these medications will receive them. Morphine is an opioid, and standard risks of opioids include nausea and vomiting. Risks of morphine may also include, but are not limited to, itching, low blood pressure, addiction and slowed breathing that may be fatal. Standard risks of clonidine include, but are not limited to, drowsiness, dizziness, slowed heartbeat, and dry mouth.

In addition, although we have worked hard to protect your privacy, there is a small risk of potential loss of confidentiality and privacy.

Will it cost me anything to participate in this research study?

There will be tests and procedures that are done only for this study and other tests and procedures that are part of your conventional medical care (not part of the research).

The sponsor, the Department of Orthopaedic Surgery at Northwestern University, will provide you with morphine and clonidine or the normal saline free of charge for this study.

You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay. In some cases, insurance will not pay for services ordinarily covered because these services were performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, the information obtained from your participation may aid our understanding and may benefit future patients as we learn more about pain management after hip arthroscopy surgery.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this institution.

All of the information collected is entered into a computer-based database that has been created by Dr. Terry. All information that includes personally identifying information, such as your name, is removed from the database and kept only in a separate database in Dr. Terry's office that does not contain any medical information. In the central database, which is kept in Dr. Terry's office, you would only be identified by a randomly assigned study number. This collected information is then available for Dr. Terry and other researchers on his team to evaluate the results of the administration of

morphine and clonidine. All paper based records will be kept in a locked cabinet in Dr. Terry's office, and they will be professionally destroyed at the conclusion of this study.

The sponsor, monitors, auditors, the IRB, the Northwestern University Office for Research Integrity, the US Office of Research Integrity, the US Office for the Protection of Human Research Protections, the US Food and Drug Administration may be granted direct access to your medical records to conduct and oversee the research. By signing this document you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

Can I be removed from the research without my OK?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include improper or incomplete data collection or if the patient is admitted to the hospital due to surgical complications.

We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

HIPAA Authorization

We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. Your health information we may collect and use for this research includes:

- All information in a medical record
- Results of physical examinations
- Medical history
- Records about study medication or drugs
- Substance abuse information:

During this study you may be coming to the [Northwestern Memorial Hospital/Northwestern Medical Group /] clinical offices for research appointments or to get clinical services, such as lab tests, needed for the study. When that happens, you will be scheduled for these services through the [NMH/NMG/] computer system. When a clinical exam or lab is done by [NMH/NMG/] or one of its employees for the purpose of this research study, that information will be kept in both [NMH's/NMG's/] clinical records and in the study records.

The following groups of people may give the researchers information about you: All current and previous health care providers, including but not limited to the, Northwestern Medical Group (NMG), Northwestern Memorial Hospital (NMH).

Once we have the health information listed above, we may share some of this information with the following people. Please note that any research information shared with people outside of Northwestern University and its clinical partners (or affiliates), the Northwestern University Institutional Review Board Office and Office for Research Integrity, the US Office of Research Integrity, the US Office for Human Research Protections, the US Food and Drug Administration will not contain your name, address, telephone or social security number or any other direct personal identifier unless disclosure of the direct identifier is necessary for review by such parties or is required

by law [except that such information may be viewed by the Study sponsor and its partners or contractors at the Principal Investigators office].

- Authorized members of the Northwestern University workforce, who may need to see your information, such as administrative staff members from the Office for Research, Office for Research Integrity and members of the Institutional Review Board (a committee which is responsible for the ethical oversight of the study).
- Clinical affiliates, including but not limited to Northwestern Medical Group (NMG), and Northwestern Memorial Hospital (NMH). Your participation in this clinical trial may be tracked in an electronic database and may be seen by investigators running other trials that you are enrolled in and by your healthcare providers.
- Clinical affiliates, including but not limited to Northwestern Medical Group (NMG), and Northwestern Memorial Hospital (NMH), for purposes including, but not limited to, the affiliate's provision of care to you and/or the affiliate's scheduling of appointments and/or billing activities.
- Other University research centers and University contractors who are also working on the study,
- Study monitors and auditors who make sure that the study is being done properly,
- Government agencies and public health authorities, such as the Food and Drug Administration (FDA) and the Department of Health and Human Services (DHHS).

Those persons who get your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

All information collected in this study will be eligible for analysis until the conclusion of the study.

Although you may revoke consent to participation in this research at any time and in any format, you must revoke authorization for use or disclosure of your health information in writing. To revoke your authorization, write to:

Michael Terry, MD

Northwestern University

Department of Orthopaedic Surgery

676 N. St. Clair, Suite 1350 Chicago, IL

You do not have to authorize the use or disclosure of your health information; however, you will not be allowed to take part in this research study. If you do not authorize the use or disclosure of your health information, it will not affect your treatment by health care providers, or the payment or enrollment in any health plans, or affect your eligibility for benefits.

A copy of this signed consent document, information about this study, and the results of any test or procedure done may be included in your medical records and may be seen by your insurance company.

Permission to Take Part in a Human Research Study

Signature of participant	Date
Printed name of participant	
Signature of person obtaining consent	Date
Printed name of person obtaining consent	