LOYOLA UNIVERSITY CHICAGO
HEALTH SCIENCES CAMPUS
MAYWOOD, ILLINOIS
DEPARTMENT OF ANESTHESIOLOGY AND PERIOPERATIVE MEDICINE

INFORMED CONSENT

Participant's Name: _____

Medical Record Number: _____

PROJECT TITLE: Complete motor sparing protocol versus Fascia Iliaca suprainguinal technique for total hip arthroplasty, a prospective randomized unblinded clinical trial.

THE APPROVAL FOR THIS PROJECT EXPIRES ON 12/15/2022.

Participant Information

About this research study
Scientists do research to answer important questions, which might help change or improve the way we do things in the future. You are being asked to participate in a research study.

Taking part in this research study is voluntary
You may choose to not take part in this study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled and will not affect your relationship with Loyola University of Chicago or Loyola University Medical Center.

This consent form will give you information about the study to help you decide whether you want to participate. Please read this form, and ask any questions you have, before agreeing to be in the study.

Overview and Key Information

This information gives you an overview of the research. More information about these topics may be found in the pages that follow.

1. **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 going to have hip replacement surgery.

2. **Why is this research being done?**

The purpose of this study is to evaluate and compare pain control in patients who undergo total hip replacement with the use of one of two types of nerve blocks: Fascia Iliaca Nerve Block or Complete Motor Sparing Nerve Block.

3. **What will happen to me during the study?**
   For our standard approach for total hip replacement, we normally do a nerve block in addition to either general or spinal anesthesia. In this study, you will have the hip replacement with general anesthesia and one of two types of nerve blocks.

   You will be assigned by lottery to one of two nerve block treatment groups: Fascia Iliaca Nerve Block group or Complete Motor Sparing Nerve Block group. You will have a 50/50 chance of being assigned to either group. We then will follow up on you regarding your pain and the amount of opioid you will need during 24 hours. For more information, please see the Description and Explanation of Procedures section below.

4. **How long will I participate?**
   Your participation in this study will last from time of consent until 24 hours after your arrival to recovery area for your total hip replacement.

5. **Will I benefit from the study?**
   We do not know if you will benefit from participating in this study. For more information, please see Benefit section below.

6. **What are the risks?**
   Taking part in this research may expose you to significant risks, which are no greater than your risk of undergoing the regular protocol. We may not know or understand all the risks at this time. Some people may experience side effects or discomfort, some of which may be serious. It is very important that you understand the known risks in this research study before you decide whether to participate. For details and a list of risks you should know about, please see the Risks/Discomforts section below.

7. **Do I have other options besides taking part in this study?**
   Participation in research is voluntary. You decide whether or not to participate. If you choose to not participate, there will be no penalty to you or loss of benefit to which you are entitled. Your doctor will discuss his or her usual practice for anesthesia for hip replacement surgery.

8. **Will I be paid to participate?**
   You will not receive any payment for taking part in this study.

9. **Will it cost me anything to participate?**
   You will not be responsible for any costs related to the research; however, you or your insurance company will still be responsible for the cost of your normal medical care. For more information, please see the Financial Information section below.

End of Overview and Key Information

Please review the rest of this document for details about these topics and additional things you should know before making a decision about whether to participate in this research.

PURPOSE OF RESEARCH: You are being asked to participate in this study because you are scheduled to undergo a total hip replacement surgery.

The purpose of this study is to evaluate and compare pain control in patients who undergo total hip replacement with the use of one of two types of nerve block; Fascia Iliaca Nerve Block group or Complete Motor Sparing Nerve Block. Both types of nerve blocks are approved and used routinely for hip replacement surgery at Loyola. This study will allow the effectiveness of two nerve block techniques to control pain to be evaluated.

The study is being conducted by Dr. Byram and the Department of Anesthesiology and Perioperative Medicine.

Approximately 40 people will participate in this research.

DESCRIPTION AND EXPLANATION OF PROCEDURES: If you agree to participate in this study by signing this informed consent form, you will be asked to do the following things:

Screening Visit: In order to determine if you qualify to take part in the study, your medical records will be reviewed.

Randomization: If you qualify for the study and you agree to continue to participate, you will be randomly assigned to one of two nerve block treatment groups:

- Fascia Iliaca Nerve Block group: Patients in this group will receive a nerve block with injection of medication at the level of the groin.
- Complete Motor Sparing Nerve Block group: Patients in this group will receive 3 injections to block 3 nerves: the cluneal nerve, the lateral femoral cutaneous nerve and the pericapsular nerve group block

The type of nerve block will differ between the two groups however the same amount of nerve block medication will be administered to both groups. Neither you nor your doctor will be able to choose which type of treatment you receive Your chances of being assigned to either or any of the treatments are 50/50; like the flip of a coin.

Administration of Nerve Block Treatment: The nerve block treatment that you were randomly assigned will be administered via ultrasound guidance in the pre-op holding area prior to your being brought to the operating room.

Hip Replacement Procedure: Once the nerve block is completed, you will proceed to the operating room where general anesthesia will be administered. Your hip replacement procedure will be conducted under an equal protocol of anesthesia for both study groups to minimize differences. All patients will receive perioperative medication the usual orthopedic protocol.

Post-Procedure: Your pain will be monitored via a numeric rating scale where 0 is no pain and 10 is the worst possible pain at the following times: immediately after arrival to recovery area post-surgery and then again at 2, 6, 12, and 24 hours. The amount of pain medication needed in those recovery 24 hours will also be recorded. Your study participation will be complete after 24 hours post recovery area arrival.

A description of this clinical trial will be available at *http://www.ClinicalTrials.gov,* as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

RISKS/DISCOMFORTS: The treatment you are assigned to receive may not help.

The treatment you are assigned to receive may be associated with more problems or may be less effective than the other treatments in this study that you did not receive.

While participating in this study, you may experience the following risks, side effect and/or discomforts: infection, bleeding, damage to nerves or close structures, local anesthetic reaction.

There may be other side effects that we cannot predict or are currently unknown.

REPRODUCTIVE AND SEXUAL ACTIVITY INFORMATION: The intervention in this study could affect a developing baby. Therefore, you cannot participate in this research project if you are pregnant or breast feeding.

If you are a woman of childbearing potential, a pregnancy test will be done to make certain that you are not pregnant before beginning the study.

BENEFITS: We do not know if you will benefit from participating in this study. The information we learn may help future patients.

ALTERNATIVE TREATMENTS: You do not have to participate in this research project to receive care and treatment at Loyola University Medical Center. You can receive the nerve blocks without participating in this research.

FINANCIAL INFORMATION: Taking part in this study may or may not cost your insurance company more than the cost of getting treatment without being in this study. Some health plan insurers will not pay the costs for people taking part in studies. Check with your health plan insurer to find out what they will pay for. Depending on your health insurance coverage, there may be out-of-pocket costs for you like co-payment of the standard visits, co-insurance, or deductibles. You will be responsible for these expenses. You or your insurance will be will be billed for the cost of all medical procedures, including the nerve block.

RESEARCH RELATED INJURY: In the event that you are injured or have side effects as a result of participating in this research project, your doctor will take the necessary steps to treat the problem. There are no funds available from Loyola University Medical Center, Gottlieb Memorial Hospital, Loyola University Health System or Loyola University of Chicago to pay for the cost of care of the problem. You will be financially responsible for the cost of care of any problems. By signing this form, you are not giving up any legal rights to seek to obtain compensation of injury.

INFORMATION COLLECTED AND WHAT WILL HAPPEN TO IT: In order to meet the goals of the research study (see Purpose of Research section of this consent), we will collect information on you, your test results, and how you do from you and your Loyola University Medical Center or Gottlieb Memorial Hospital medical records. The information will be collected by Dr. Byram, the study physicians, the research nurses, data administrators and secretaries.

Information about you will be provided to Loyola University of Chicago, statistician; data collection and study verification agencies.

In this way, we will learn about how to achieve better pain control for the hip replacement surgery.

The information we will collect includes:

__X__ DEMOGRAPHIC INFORMATION (e.g., name, address, phone number)

__X__ MEDICAL RECORD (including, but not limited to, history and physical exam notes, progress notes, consultation reports, laboratory test results, AND/OR operative reports)

__X__ PHOTOGRAPHS, VIDEOTAPES, OR DIGITAL OR OTHER RADIOGRAPHIC IMAGES (ultrasound images)

We will collect and provide this information about you for as long as you are in the study.

Once the information is disclosed outside of Loyola University Medical Center or Gottlieb Memorial Hospital, it may no longer be protected by federal privacy laws.

De-identified data from this study may be shared with others for research purposes. We will remove or code any personal information that could identify you before data are shared with other researchers to ensure that no one will be able to identify you from the information we share, however this cannot be guaranteed. Once identifying information is removed, the information and samples cannot be withdrawn from further use. You will not be asked to sign an additional consent for this use.

It is possible that the research nurses, data collection and/or study verification agencies, data administrators or staff will come to Loyola University Medical Center or Gottlieb Memorial Hospital and view the medical record (see above for description of content) and the research records. They may take notes or copy pages of the medical record. This is done to verify the accuracy of the information Loyola University of Chicago is sending to them.

The results of this research study may be published in a journal for the purpose of advancing medical knowledge. You will not be identified by name or by any other identifying information in any publication or report about this research.

Consent for LUMC to use and disclose your medical information is required in order for you to participate in the study.

This authorization does not expire.

WITHDRAWAL OF CONSENT: Your consent to use and disclose your medical information for the purpose of this research study is completely voluntary. You can withdraw your consent to use and disclose your information and your consent to participate in this study at any time without affecting your ability to receive care and treatment at Loyola University Medical Center or Gottlieb Memorial Hospital, as applicable, unrelated to the research study. Withdrawal means that all study procedures and follow-up will stop and we will not send any more information about you to the sponsor of this research or its designees. However, information already used and disclosed to the research sponsor prior to the time of your withdrawal from this study may continue to be used and disclosed by Loyola University of Chicago.

If you withdraw from the study, we will ask that you sign the form attached to this consent and send it to Dr. Byram or give it to the study staff. Your withdrawal from the study will not have any effect on any actions by Loyola University Medical Center, Gottlieb Memorial Hospital, or Loyola University of Chicago taken before the attached form is received by Loyola University of Chicago.

Your study doctor, the Institutional Review Board, the regulatory authorities may terminate the study at any time with or without your consent.

Your study doctor may choose to take you out of the study because of unexpected or serious side effects, better management of pain with different technique, or allergies. You may also be removed from the study if your study doctor feels that you are not benefiting from the study treatment.

CONSENT

I have fully explained to _____ the nature and purpose of the above-described procedure and the risks that are involved in its performance. I have answered and will answer all questions to the best of my ability. I may be reached at 708-216-8866.

_____Date:____/_____/____
Signature

Dr. Byram the principal investigator for this study, or Dr. Martinez Parra, his associate will be available to answer any questions you may have. Both doctors can be reached at 708-216-8866.

If you ever feel that you have been injured by participating in this study or if you have any questions concerning your rights as a research participant, you may contact either Kenneth Micetich, MD, Chair of the Institutional Review Board for the Protection of Human Subjects-Loyola University Chicago Health Sciences Campus, at 708-216-2633 or Cynthia Tom-Klebba, MA, CIP, Director of the Human Research Subjects Protection Program at 708-216-4608.

Although you have the right to revoke this authorization, you accept that such revocation will not apply to any uses and disclosures of your information that are described in the Loyola University Health System Notice of Privacy Practices or otherwise allowable under any Federal or State laws.

You will receive a signed copy of this informed consent document.

You have been fully informed of the above-described research program with its possible benefits and risks. Your signature below indicates that you are willing to participate in this research study and agree to the use and disclosure of information about you as described above. You do not give up any of your legal rights by signing this consent document.

_____Date:____/_____/____
Signature: Participant

PROJECT TITLE: Complete motor sparing protocol versus Fascia iliaca suprainguinal technique for total hip arthroplasty, a prospective randomized unblinded clinical trial.

REVOCATION OF AUTHORIZATION TO
RELEASE PROTECTED HEALTH INFORMATION (PHI)

I, _____, hereby revoke my consent to participate in the study titled, "Complete motor sparing protocol versus Fascia iliaca suprainguinal technique for total hip arthroplasty, a prospective randomized unblinded clinical trial", at Loyola University Medical Center, Gottlieb Memorial Hospital, or Loyola University of Chicago, as applicable. I also revoke my consent to release information I provided to Loyola University Medical Center, Gottlieb Memorial Hospital, or Loyola University of Chicago, as applicable, that allowed use and disclosure of my medical information to Department of Anesthesiology and Perioperative Medicine as outlined on the consent form, which I signed on ____/_____/____ (INSERT DATE CONSENT WAS SIGNED ORIGINALLY). I understand that this revocation does not apply to any action Loyola University Medical Center, Gottlieb Memorial Hospital, or Loyola University of Chicago, as applicable, have taken in reliance on the consent I signed earlier.

_____Date:____/_____/____
Signature: Participant

Please return this form to:

Scott Byram, MD
Department of Anesthesiology and Perioperative Medicine
Loyola University of Chicago
2160 South First Avenue
Maywood, Illinois 60153