Efficacy of Ketorolac for Postoperative Pain Management in Hip Arthroscopy: A Prospective Randomized Controlled Trial

NCT05965310

Date: 03/05/2024

INFORMED CONSENT TO PARTICIPATE IN A RESEARCH STUDY

HENRY FORD HEALTH	Participant Name: MRN: Date:
PROJECT TITLE: Efficacy of Ketorolac for Postoperative Pain Management in Hip Arthroscopy: A Prospective Double Blinded Randomized Controlled Trial **Protocol Version # and Date:** Ver 1, 8/29/2023	

Principal Investigator (PI): Dr. T. Sean Lynch
PI Address: 690 Amsterdam St. Detroit, MI 48202
PI Phone: 800-436-7936

1. **INTRODUCTION**

You are being asked to participate in a research study. The box below highlights key information about this research for you to consider when deciding whether or not to participate. More detailed information is provided in the body of the consent. No research activity is to be conducted until you have had an opportunity to review this consent form, ask any questions you may have, and sign this document.

Key Information for You to Consider
Voluntary Consent. You are being asked to participate in a research study because of your upcoming hip surgery. Participation is optional. There will be no penalty or loss of benefits if you choose not to participate or discontinue participation. **Purpose**. The purpose of this research is to investigate the impact of a medication called ketorolac on your pain after hip arthroscopy. **Duration**. It is expected that your participation will last up to 3 months after surgery. **Procedures and Activities**. If you choose to enroll, you will be randomly selected into two groups. Both will receive Dr. Lynch's typical pain medications for after hip arthroscopy, however one will also receive a course of ketorolac. In a journal, which will be provided, you will record your pain levels multiple times a day and how often you take your opioid pain medication for 5 days total. You will also complete surveys throughout your postoperative care which are given to all orthopedic surgery patients. **Risks**. Some of the inconveniences of your participation include filling out a pain journal, possible side effects from ketorolac, and contact by study personnel. There

are risks associated with using ketorolac which are similar risks to using other non-steroid anti-inflammatory drugs (NSAIDS), like ibuprofen. More detailed information can be found in the "*What are the Risks, Discomforts, and Inconveniences of Participating in the Study?*" section in the Consent Form.

Benefits. Some of the benefits that may be expected include improved pain after surgery without the side effects and risk of opioid addiction. The information learned from your participation in this study will also benefit hip arthroscopy patients in the future.

Alternatives. Participation is voluntary, and the only alternative is to not take part in this research study.

2. DISCLOSURE OF POTENTIAL CONFLICT OF INTEREST

The Henry Ford Health (HFH) investigator(s) on this study are also healthcare providers. They are interested in the knowledge to be gained from this study and are interested in your well-being. They have no financial incentive

3. WHY IS THIS RESEARCH BEING DONE?

You have been asked to take part in a research study because you are having a Hip Arthroscopy (HA) surgery.

A total of 80 people will be enrolled.

The purpose of this research study is to determine the impact of ketorolac for pain management after hip arthroscopy and determine if it is better than current medications for controlling postoperative pain and if it reduces opioid medication consumption.

4. WHAT WILL HAPPEN IF I TAKE PART IN THIS RESEARCH STUDY?

There will be two groups in the study. You will be randomized into one of the study groups described below. Randomization means that the group you are assigned to will be chosen by chance, like flipping a coin). A computer program will place you in one of the two study groups. Neither you nor your doctor can choose the group you will be in. You will have an equal chance of being placed in either group.

If you are in group 1 (often called "Arm A" or the 'treatment group'), you will receive a dose of ketorolac through your IV during surgery and receive ketorolac pills after surgery to take for three days in addition to our standard pain medications. We also will give you omeprazole to help prevent stomach pain.

If you are in group 2 (often called "Arm B" or the 'control group'), you will the standard pain medications.

Both groups will record their pain levels and opioid usage in a journal for 5 days after surgery as well as complete surveys at specific time points before and after surgery. We will collect the journal from you at your first office visit.

5. **WHAT ARE THE RISKS, DISCOMFORTS, OR INCONVENIENCES OF PARTICIPATING IN THE STUDY?**

Ketorolac is a non-steroidal anti-inflammatory (NSAID) which is in the same family of drugs as ibuprofen (Advil) and naproxen (Aleve). It has similar risks to those commonly used drugs such as possible stomach pain, heartburn, vomit that is bloody or looks like coffee grounds, blood in stool, or black and tarry stools. If any of these occur, contact the office. If you are on blood thinners, have stomach ulcers, kidney disease, an allergy to NSAIDs, chronically use opioids, and/or have an alcohol or drug disorder you are not a candidate for the study.

Other inconveniences include recording your pain levels three times a day for 5 days after surgery, recording your medication usage for 5 days after surgery, contact by study personnel, and completing surveys before and after surgery.

Additional risks include a potential breach of confidentiality of your personal information. The measures taken to protect your personal information and any possible disclosure are described in the section below titled "*How will my personal information be protected*?"

6. **WHAT ARE THE BENEFITS TO TAKING PART IN THE STUDY?**

The benefits of participating in this study may include better control of pain after hip arthroscopy and fewer opioid pills taken. However, there is also a chance you may not directly benefit from this research, but what we learn may help others in the future.

7. **WHAT OTHER OPTIONS ARE THERE AND WHAT ARE MY ALTERNATIVES?**

An alternative treatment to the one discussed in this study is to adhere to the current postoperative pain management protocol for hip arthroscopy set by Dr. Lynch. The patient will be provided all standard of care medications in addition to the study treatment.

8. **HOW WILL MY PERSONAL INFORMATION BE PROTECTED?**

Research records will not include names, registration numbers, or other information that is likely to allow someone other than the researchers to link the information to you. The researchers will label research records with a unique code and keep any master key that links your name and data and/or specimens in a separate location. The researchers

will maintain all study records (including any codes) in a locked, secure location. Your research information will not be made a part of your regular medical record. If the researcher orders any tests, the order and results may become part of your regular medical record. All electronic files containing identifiable information will be password protected and only the members of the research staff will have access to the passwords. If researchers share your data and/or specimens with others, the information will be coded as described above to help protect your identity. At the conclusion of this study, the researchers may publish their findings. Information will be presented in summary format, and you will not be identified in any publications or presentations. The researchers will maintain any data described in this paragraph in accordance with the security provisions of this paragraph until destroyed by the researchers after conclusion of the research study.

Specific Protections Include:
Confidentiality Agreements: All users of the data will sign confidentiality agreements and receive training on proper procedures for how to handle patient level data.

System Controls to Limit Data Access: Only authorized personal will be given permission to access study data.

Computer System Security Plan: A security plan exists within the organization to provide protection for patient level data.

Virus Protection Software: A virus protection software is in place within the organization to protect patient level data.

Firewall: The organization's network system is protected by a firewall. The computer systems in place will have the operating system firewall in place.

Computer Locking: The computer(s) have automatic locking after 20 minutes of inactivity. Computer System are password protected with duo activation.

Physical Security: Physical access to servers and computers are restricted to only authorized personnel. The computer system is in a room which is inaccessible to the public.

Secure Electronic Copies: All electronic copies of patient level data will be secured to a room for authorized personnel only.

Secure Paper Copies: All paper copies of patient data will be kept under lock and key in a room accessible to only authorized individuals.

You should also know that the HFH Institutional Review Board (IRB) and IRB Administration Office may inspect study records as part of its auditing program, but

these reviews only focus on the researchers. The IRB is a group of people who review research studies to protect the rights and welfare of research participants.

Your identifiable private information, even if stripped of identifiers, will not be used for future research studies or distributed to another researcher for future research studies without additional informed consent.

9. **WHAT IF I GET SICK OR I AM INJURED?**

There is no federal, state, or other program that will pay you or pay for your medical care if you are injured as a result of participating in this study. You and/or your medical insurance may have to pay for your medical care if you are injured as a result of participating in this study.

By signing this consent form, you do not give up any of your legal rights in the event of an injury.

10. **WHO DO I CONTACT WITH QUESTIONS ABOUT THE STUDY OR TO REPORT AN INJURY?**

Dr. T. Sean Lynch, or his staff members has explained this research study and has offered to answer any questions. If you have any additional questions about the study procedures, or to report an injury you may contact Dr. T. Sean Lynch or his research personnel by phone at 800-436-7936 or by email mgaudia1@hfhs.org. Medical treatment is available to you in case of an injury.

If you would like to discuss your rights as a research participant, report problems or concerns, ask questions, obtain additional information, or offer input with an informed individual who is unaffiliated with the research study, you may contact the Henry Ford Health IRB Administration Office by phone at (313) 874-4464 or by email at research_admin@hfhs.org.

11. **DO I HAVE TO PARTICIPATE IN THIS STUDY?**

You do not have to be in this study if you do not want to. If you agree to be in the study, but later change your mind, you may drop out at any time. Inform the research staff/study doctor if you are thinking about stopping or decide to stop. There are no penalties or loss of benefits to which you are otherwise entitled if you decide that you do not want to participate.

If choose to stop participating or have side effects from medications, you may be asked to return for a visit for safety reasons. You will get the same medical care from HFH whether or not you participate in this study. You will be told about any significant

information that is discovered that could reasonably affect your willingness to continue being in the study. You will be notified of all significant new findings during the course of the study that may affect your willingness to continue.

You do not have to answer any questions that you do not want to answer.

12. WHO ELSE CAN STOP MY PARTICIPATION?

The PI, sponsor, or your doctor can end your participation in the research study at any time. If this happens, you may be asked to return for a visit for safety reasons.

13. WILL IT COST ANYTHING TO PARTICIPATE?

There will be minimal or no charge to you for your participation in this study. Ketorolac is a common pain medication and is likely covered by health insurance. The journal will be provided at no charge. You will still be responsible for the cost of your usual ongoing medical care, including typical standard-of-care rehabilitation after your surgery. You have the right to ask what it will cost you to take part in this study. If you have any questions about the costs of this study, please ask the study doctor, or a member of the study staff.

While some of the tests and exams may be considered standard of care, they may or may not be covered by your medical insurance. You may be responsible for insurance co-payments. If your medical insurance does not pay for your care, you may be responsible for the cost of the medical care related to your condition including but not limited to: laboratory tests, deductibles, co-payments, physician and clinic fees, hospitalization, and procedures.

14. WILL I BE PAID TO PARTICIPATE?

There is no compensation being offered for your participation in this study.

DOCUMENTATION OF CONSENT

By signing this form, I agree that I have read and understand this form and that I agree to participate in the research project described above. I have been given enough time and opportunity to ask about the details of the research study and to decide whether or not to participate. Its general purposes, the particulars of my involvement and possible risks and inconveniences have been explained to my satisfaction. I understand that I can withdraw at any time without giving any reason without my medical care or legal rights being affected. My signature also indicates that I have received a copy of this consent form.

The researchers in this study might want to ask you to participate in additional studies. In some cases, you might be a good candidate for a particular study because of your health history or genetic information.

I am willing to be contacted for participation in future research studies. Please initial below.

_____ I agree

_____ I refuse

My deidentified data may be stored and used for future research. Please initial below.

_____ I agree

_____ I refuse

_____ _____ _____

Signature of Participant Date Time

_____

Printed Name of Participant

_____ _____ _____

Signature of Witness to Consent* Date Time

_____

Printed Name of Witness*

_____ _____ _____

Signature of Person Obtaining Consent Date Time

_____

Printed Name of Person Obtaining Consent

INFORMATION ABOUT CONFIDENTIALITY AND HIPAA AUTHORIZATION

A federal regulation, known as the Health Insurance Portability and Accountability Act (HIPAA) gives you certain rights concerning the use and disclosure (sharing with others) of your Protected Health Information (PHI). This regulation provides safeguards for the privacy and security of your information. Your permission (authorization) is required for the use and sharing of any PHI collected as part of this research study. If you are not willing to sign this authorization to use and/or disclose your PHI by the research team, you will not be eligible to take part in this research study.

The Principal Investigator (PI) and his research team will use your medical records and information created or collected as part of this research study. Your PHI is important for the PI and his research team to collect information about you during the study, to be able to contact you if needed, and to provide treatments to you during the study, if required. The PI may send out your study related health information to the sponsor or other entities involved in this study.

We will collect and use:

- Demographic information.
- Test results
- Medical history
- Diagnostic and medical procedures
- Imaging

This health information may contain your name, address, phone number, email address, date of birth, medical record number, unique characteristics or code, pre-operative questionnaire scores, and medication history.

We may release this information to the following people:

- The Principal Investigator and his/her associates who work on or oversee the research activities.
- Henry Ford Health Institutional Review Boards (IRB)
- Government agencies and officials who oversee research (e.g., FDA, OHRP, OCR, etc.).
- Your insurance company or others responsible for paying your medical bills.
- Other researchers at other institutions participating in the research.

Once your information has been released according to this Authorization, it could be released again and may no longer be protected by federal privacy (i.e., HIPAA) regulations.

This Authorization, any test results, medical reports and other information about you from this study may be placed into your medical record. Generally, you are allowed to look at your medical record. During the research study, you will not be allowed to look at the research study information that is not in your medical record.

No names, identifying pictures or other direct identifiers will be used in any public presentation or publication about this study unless you sign a separate consent allowing that use.

This Authorization to use and release your personal protected health information does not expire.

You do not have to sign this Authorization and may cancel it at any time. If you decide to cancel your Authorization at later date, you will not be able to continue to participate in this study. If you withdraw your permissions, we may continue to use and release the information that has already been collected. To cancel your consent, send a written and dated notice to the following:

Dr. T. Sean Lynch
690 Amsterdam St, Detroit, MI 48202

By signing this document, you are authorizing the PI to use and disclose PHI collected about you for the research purposes as described above.

_____ _____

Signature of Participant Date Time

_____

Printed Name of Participant

For participants unable to give Authorization, the following individual is acting on behalf of the research participant (e.g., children, cognitively impaired, etc.).

_____ _____

Signature of Legally Authorized Representative Date Time

_____ _____

Printed Name of Legally Authorized Representative Relationship to Participant