Informed Consent Document

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Defining Normal Postoperative Magnetic Resonance Imaging after Total Knee Arthroplasty

BENAROYA RESEARCH INSTITUTE
Virginia Mason

Defining Normal Postoperative Magnetic Resonance Imaging after Total Knee Arthroplasty

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

IRB Number: **IRB18-008**

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You are being asked to participate in an investigational study. Your study doctor will explain this investigational study to you. Investigational studies include only people who choose to take part. You are being asked to take part in this study because you are scheduled to have knee replacement surgery and a nerve block for pain management after the operation. This particular investigational study in humans is designed by the investigators, Drs. Neal, Blackmore, and Verdin.

The following is a summary of the information you were given when this study was discussed with you. You may discuss your decision with your friends and family. You can also discuss it with your health care team. If you have any questions, you can ask your study doctor for more explanation.

WHY IS THIS STUDY BEING DONE?

The purpose of this investigational study is to determine: 1) what magnetic resonance imaging (MRI) of your upper leg looks like after an uneventful total knee replacement (TKR) surgery, and 2) what happens to levels of creatine phosphokinase and aldolase after the same surgery (CPK, and aldolase, are enzymes in your blood that serve as a markers of muscle inflammation and/or injury).

These tests are of interest to us because of a recently described complication called local anesthetic-induced myotoxicity (LAIM). In the last 5 years of performing TKR at Virginia Mason Medical Center we have observed LAIM in about 1 of every 1000 TKR procedures. The complication is associated with profound weakness of the surgical leg's quadriceps muscles (the muscles in the front of your thigh), which develops the day after surgery. Most of our affected patients have gone on to have full or nearly full recovery of their muscle strength, but the recovery process takes several weeks and thus impacts their rehabilitation after TKR. We believe this complication is most likely related to muscle damage caused by the local anesthetic that is given as part of the nerve block, which is placed to improve your pain after surgery. This nerve block is called a continuous adductor canal block (CACB).

This complication has never been described before after TKR. Indeed, before this, LAIM was thought to only occur in humans in about one-half of 1% of nerve blocks used for eye surgeries. Because this is a new complication, we know very little about what causes it or how to diagnose it. All patients under our care who have experienced LAIM have shown MRI signs of inflammation and swelling in their upper, operated-on leg. However, we do not know for certain that the changes we have seen on their MRI are indeed not just changes that may occur normally after a TKR procedure. Similarly, we do not know what happens to a patient's CPK levels after this surgery.

The goal of this study is to determine what defines "normal" MRI appearance and CPK levels after TKR.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

About 20 people will take part in the study at Benaroya Research Institute at Virginia Mason.

WHAT IS INVOLVED IN THE STUDY?

Participation in this study involves two interventions; neither of which routinely happen during the care of a TKR patient.

- First, a baseline CPK and aldolase levels will be obtained as part of your routine pre-operative blood work. If you have a normal post-operative course after your TKR surgery, follow-up CPK and aldolase levels will be obtained before you leave the hospital.
- The second part of the study, assuming your postoperative course has been normal, is having an MRI obtained of your operated-on upper leg either the afternoon of the day after your surgery, prior to your leaving the hospital for home.

HOW LONG WILL I BE IN THE STUDY?

You will be in the study for 2 days – the day of your surgery plus one day in the hospital after your surgery

The researcher may decide to take you off this study if there is evidence the muscle function of your operated-on leg is less than what would normally be expected, or if we discover a previously unrecognized reason that would prevent you from having an MRI.

You can stop participating in the study at any time. If you decide to stop being in the study, please talk to the researcher (Dr. Neal) and your orthopedic surgeon (Dr. Verdin) first.

WHAT ARE THE RISKS OF THE STUDY?

While on the study, you may be at risk for:

- Some, but not all, patients continue local anesthetic infusion via the adductor canal catheter overnight the day after surgery. This means that they either go home with a portable pump or have the infusion continued in the hospital for the second night after surgery. Because the catheter must be removed prior to undergoing an MRI, your catheter will be removed just prior to entering the scanner. Thereafter, your pain control will be accomplished using oral pain medications, just as would normally occur (with or without continuation of the adductor canal catheter).
- Some patients can become claustrophobic or have anxiety during an MRI.
- The small risk of bruising, infection, or discomfort associated with obtaining blood for the CPK and aldolase analyses. We will make every attempt to coordinate the drawing of these specimens with blood draws routine to your operation.

You should discuss these with the researcher and/or your regular doctor. There also may be other side effects or risks that we cannot predict. Other drugs or procedures may be given or performed to make side effects less serious and uncomfortable, such as if you have an allergic reaction to the x-ray dye. Many side effects go away on their own, but in some cases side effects can be serious or long lasting or permanent.

Risks and side effects related to the MRI include:

Likely:

- Noisy environment.

Rare but Serious:

- Burns or disruption of metallic implants within your body (having such implants will disqualify you from having an MRI).
- Claustrophobia or anxiety during the scan.

The risks of blood drawing include: fainting, the occurrence of temporary discomfort and/or bruise at the site of puncture; rarely, infection or the formation of a small clot or swelling to the vein and surrounding area may occur.

For more information about risks and side effects, ask the researcher or contact Dr. Neal at 206-223-6980.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there are no benefits directly to you. We hope the information learned from this study will benefit other people who may develop LAIM the future.

Participants who complete the study will be awarded a $50 stipend.

WHAT OTHER OPTIONS ARE THERE?

You may choose not to participate in this study. Instead of being in this study, you can have your knee replacement surgery without undergoing the MRI exam or CPK/aldolase blood tests.

WHAT ARE THE COSTS?

Taking part in this study (having the CPK and aldolase blood analysis, and the MRI exam) will not lead to added costs to you or your insurance company. All other costs are considered standard of care and will be billed to you and your insurance company as per usual. This study does not provide funds for co-pays that are part of standard of care visits.

Participants will be given $50 for taking part in this study.

WHAT IF YOU GET INJURED BECAUSE YOU TOOK PART IN THIS STUDY?

It is important you tell your study doctor, Joseph M. Neal, MD if you feel you have been injured because of taking part in this study. You can tell the doctor in person or call him at 206-223-6980.

You will get medical treatment if you are injured as a result of taking part in this study. You and/or your health plan will be charged for this treatment. No funds have been set aside to compensate you in the event of injury.

You or your insurance company will be charged for continuing medical care and/or hospitalization.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

Taking part in this study is voluntary, and you may choose not to take part or may leave the study at any time. Choosing not to take part or leaving the study will not result in any penalty or loss of benefits to which you are entitled outside of this research.

Joseph M. Neal, MD will tell you about new information that may affect your health, welfare, or willingness to stay in this study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

- For questions about study procedures, study costs, or to report a study-related injury, contact the researcher, Joseph M. Neal, MD at 206-223-6980.
- For questions about your rights as a research participant, contact the BRI Institutional Review Board (IRB) Manager at (206) 342-6916. The IRB Administrator manages the IRB, which is a group of people who review this research to protect your rights and welfare.

WHERE CAN I GET MORE INFORMATION?

You will get a copy of this consent form. You may also request a copy of the protocol (full study plan).

If you request, we will reveal to you the results of your MRI exam and/or your blood results once all subjects have completed the study. If you request, we will provide you a copy of the study results if they become published. Should the study by published, nothing in the paper will identify you as one of the subjects.

AUTHORIZATION TO USE AND/OR DISCLOSE PROTECTED HEALTH INFORMATION FOR RESEARCH

We are required by special federal and state privacy laws to protect the privacy of your health information under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule. Researchers (investigators) would like to use your health information for research. This section describes what researchers will do with information about you. To learn more about your individual privacy rights, you may ask your provider for a Notice of Privacy Practices.

WHAT IS PROTECTED HEALTH INFORMATION (PHI)?

PHI is information gathered by a health care provider, health plan, or researcher that identifies you or which includes facts that may tie your identity to your health record.
PHI includes:

- Information from your existing or future medical records needed for this study as described in this form; *and/or*
- Information about you created during this study, as described above.
- This health information generally includes: demographics information, result of physical exams, histories and physicals, X-rays, diaries, questionnaires, records of treatments and side effects of treatments, and in regard to this study also includes: CPK blood levels

WHO MAY USE OR SHARE MY PHI?

You should understand that participating in this investigational study does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

WHAT MAY THE RESEARCHERS DO WITH MY PHI?

The researchers will use your health information to conduct the research. As part of the research they may share your information with certain people and groups. These may include:

- The Institutional Review Board (IRB) that approved this research, Benaroya Research Institute (BRI) IRB. The IRB reviews, audits, and monitors studies to protect the rights and safety of research participants.
- BRI Regulatory Compliance and Education Department will conduct routine internal quality reviews audits and monitor visits of the study and patient records.
- Government and public health agencies, their representatives, and others as required by law.
- Your health insurer(s) if they are paying for care provided as part of the research.

HOW WILL MY HEALTH INFORMATION BE KEPT PRIVATE?

All efforts will be made to keep your personal information confidential; however, we cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law.

Researchers generally remove your name (and other information that could identify you) from your health information before sharing it. Once your PHI is given to a third party, that party may share it with someone else and the federal privacy law may no longer protect it; however, other privacy protections may still apply.

If research findings are published from this study, they will not identify you unless you allow it in writing.

WHAT HAPPENS IF I WANT TO WITHDRAW MY AUTHORIZATION?

You may change your mind at any time and withdraw this authorization. This request must be made in writing to the investigator Joseph M. Neal, MD at the address listed on page 1 of this form. Beginning on the date you withdraw, no new identifiable health information will be used for research. However, the researchers may continue to use and share the information that was provided before you withdrew your permission. If you withdraw your authorization, you will not be allowed to continue in this research study.

HOW LONG WILL THIS AUTHORIZATION LAST?

If you agree by signing this form, the researchers can use and share your identifiable health information indefinitely. The authorization will not expire unless you withdraw your permission as directed above.

PATIENT'S AUTHORIZATION

I have read and been given a chance to ask questions about this consent form and HIPAA authorization and agree to take part in this study. My signature indicates that I have been given a copy of this consent form and HIPAA authorization.

_____	_____	_____
PARTICIPANT'S SIGNATURE	**PARTICIPANT'S NAME** (print)	**DATE**

CERTIFICATE OF PERSON OBTAINING CONSENT:

I have provided an explanation of the above research study, and have encouraged the subject to ask questions and request additional information regarding the study and possible alternatives. A copy of this consent form has been given to the subject.

SIGNATURE OF PERSON OBTAINING CONSENT

NAME OF PERSON OBTAINING CONSENT (print)

DATE

cc: Participant and Investigator's File