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Henry Ford Health System	**INFORMED CONSENT TO PARTICIPATE IN A RESEARCH STUDY** (HFH IRB form rev: 6/6/2019)	DATE: MRN: NAME:
APPROVAL PERIOD Mar. 10, 2020 – Mar. 9, 2021 INSTITUTIONAL REVIEW BOARD	**PROJECT TITLE:** **Oral Dexamethasone as an intervention for postoperative pain and nausea management in total knee arthroplasty patients**	

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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 making a decision whether or not to participate. More detailed information is provided after the box. 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. Participation is voluntary. 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 assess if oral dexamethasone provides added benefits to managing postoperative pain and nausea in patients receiving total knee arthroplasty.

Duration. It is expected that your participation will last about 6 months following surgery, with 2 follow-up visits at 3 weeks and 6 months as standard.

Procedures and Activities. You will receive either an oral placebo pill or a 4mg dose of oral form of dexamethasone, which you will take for four days after surgery. Your pain score and current pain medications will be collected before your first dose of the placebo or the dexamethasone. Your pain and nausea scores will be collected following surgery, as well as your opioid and antiemetic (anti-nausea medication) consumption. You will be expected to complete a pain and nausea journal following your surgery.

Risks. Some of the foreseeable risks or discomforts of your participation include expected side effects of taking dexamethasone. More detailed information can be found in the "*What Are The Risks, Discomforts, And Inconveniences Of The Study?*" section in the Consent Form.

Benefits. You may or may not directly benefit from this research. Patients who receive oral dexamethasone could benefit by experiencing reduced pain and episodes of nausea. Additionally, the information learned from your participation may help others in 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 System (HFHS) 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. Investigators may obtain salary or other financial support for conducting the research.

3. WHY IS THIS RESEARCH BEING DONE?

You have been asked to take part in a research study because you will be undergoing a total knee arthroplasty

The purpose of this research study is to assess if oral dexamethasone provides added benefits to managing postoperative pain and nausea in patients receiving total knee arthroplasty.

As part of this study, you will receive either no additional treatment or an oral dexamethasone to determine if oral dexamethasone is beneficial for managing postoperative pain and nausea.

A total of people 300 people will be enrolled at Henry Ford Health System (HFHS).

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

If you agree to take part in this study, your participation in this study will last a total of 6 months up, with 2 follow-up visits at 3 weeks and 6 months as standard. As part of this study, you will receive

either a placebo medication or the oral form of 4mg dexamethasone. You will have to take your assigned medication for four days after surgery. This will be in addition to routine care and pain medication regimen normally offered following your joint replacement. Your pain and nausea scores will be recorded along with your opioid and antiemetic consumption. You will be expected to record your joint pain, your pain medication and the associated activity in pain journal at home. You will be provided with the medications you need to control your pain postoperatively. You will not be allowed to use any other medications other than the ones given to you at discharge. Any concerns regarding pain control can be addressed at your follow-up visit with your surgeon. The dose of medications and protocol of postoperative care followed for either form are similar. This will not affect the standard postoperative course after surgery. You will not need any additional follow-up beyond what is normal for total knee replacement. No extra labs or medications will be administered. You will receive the standard of care for total knee replacement, including being discharged from the hospital after clearing physical therapy.

For some research studies, including the one you are being asked to join, you will be given the results of certain tests including postoperative images and lab tests run as part of your postoperative care. These results will be available to you via MyChart or will be communicated to via phone call from the clinic and to be discussed during postoperative visits.

There will be 2 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 study groups. Neither you nor your doctor can choose the group you will be in. You will have an equal one in two chance of being placed in either group.

If you are in group 1 (often called "Arm A"), you will be given a 4 day course of placebo pills

If you are in group 2 (often called "Arm B"), you will be given a 4-day course of 4 mg oral dexamethasone to take home with you.

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

While you are in the study, you are at risk for the following side effects associated with use of steroids:

Likely
• Hypertension (Diabetic macular edema, 13%), Cushing's syndrome, Decreased body growth, Abnormal vision (1% to 9%), Cataract (Diabetic macular edema, 68%; retinal vein occlusion and uveitis, 5% to 54%), Conjunctival edema (5%), Conjunctivitis (6%), Corneal edema (Postoperative ocular pain, 1% ; postoperative inflammation, 5% to 15%), Discomfort, Eye (10%), Disorder of anterior chamber of eye, Inflammation (9%), Dry eye syndrome (5%), Iridocyclitis, Iritis (5% to 15%), Raised intraocular pressure (Retinal vein occlusion and uveitis, 24% to 25% ; postoperative inflammation, 5% to 15% ; postoperative pain, 5%), Vitreous floaters (1% to 5%),Depression, Euphoria, tuberculosis
Rare but Serious
• Acute myocardial infarction with rupture of ventricle, Cardiomyopathy, Hyperglycemia, Hypokalemia, Pancreatitis, Immunologic: Infectious disease, Osteoporosis, Conjunctival hemorrhage (Diabetic macular edema, 23%; retinal vein occlusion and uveitis, 22%), Glaucoma (Diabetic macular edema, 1.2%), Keratitis (2%), Posterior subcapsular cataract, Retinal tear (2%), Retinal vascular disorder (3%), Uveitis (2%)

The researchers will try to minimize these risks by monitoring for adverse side effects and paying attention to your current medications and any potential drug interactions.

There may be additional risks or discomforts that are not known at this time. Being in more than one research study at the same time, or even at different times, may increase the risks to you. It may also affect the results of the studies. You should not take part in more than one study without approval from the researchers involved in each study. If you are currently in another study, took part in one recently, or if you consider another study in the future, please inform the research staff right away.

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?

You may not directly benefit from this research; however, if you do receive the oral dexamethasone medication you could benefit by experiencing reduced pain and episodes of nausea. Additionally, we hope that others are helped in the future by what is learned.

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

Participation is voluntary. You do not have to participate in this study. Whether or not you participate in the study you will have access to the current standard of care for total knee replacement at Henry Ford Hospital. You may withdrawal from the study at any time.

You can talk to your doctor about your choices before you decide if you will take part in this study.

8. HOW WILL MY PERSONAL INFORMATION BE PROTECTED?

By signing this consent form, you agree that we may collect, use and release your personal and health information for the purpose of this research study.

This consent form, test results, medical reports and other information about you from this study may be placed into your medical record. You can look at your medical record.

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.

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 with others, the information will be coded as described above to help protect your identity. The researchers will maintain any data described in this paragraph in accordance with the security

provisions of this paragraph until destroyed by the researchers. Anonymized records will be kept indefinitely.

HFHS or others may publish the results from this study. 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 allow that use.

This consent to use and releases your personal and health information will expire at the end of this research study.

You do not have to sign this consent to release your medical information and may cancel it at any time. If you decide not to sign this consent or cancel your consent, you cannot participate in this study. If you notify us that you wish to stop participating in this study, 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 principal investigator at the address listed on the first page of this form.

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

There is no federal, state, or other program that will compensate 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. Jason Davis, a member of the research team or a staff member 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 at the research team at hfjointreplacement@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, discuss problems, concerns, and questions; obtain information; or offer input with an informed individual who is unaffiliated with the specific research, you may contact the Henry Ford Health System IRB Administration Office by phone

at (313) 874-4464 or by email at research_admin@hfhs.org. The IRB is a group of people who review the research to protect your rights.

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.

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. You do not have to answer any question 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?

We do not expect there to be any additional costs to you if you participate in this study. Items related to the routine medical care that you would receive even if you did not participate in this study will be billed to you or your insurance company. You have the right to ask what it will cost you to take part in this study.

14. WILL I BE PAID TO PARTICIPATE?

There is no compensation available to you for your participation in this study.

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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 future research studies. Please initial below.

_____ I agree

_____ I refuse

_____ Signature of Subject	_____ Date	_____ Time
_____ Printed Name of Subject		
_____ Witness to Signature	_____ Date	_____ Time
_____ Signature of Person Obtaining Consent	_____ Date	_____ Time
_____ Printed Name of Person Obtaining Consent		