**Participant Information Statement**

*Orthopaedic Research Institute of Queensland*

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| --- | --- |
| **Title** | Lateral skin incision, reduces skin dysaesthesiae and improves kneeling post total knee arthroplasty: A Randomised Controlled Trial in Simultaneous Bilateral Total Knee Arthroplasty |
| **Short Title** | Lateral incision and kneeling study in Bilateral TKRs |
| **Protocol Number** | Version 2.3 |
| **Project Sponsor** | ORIQL |
| **Coordinating Principal Investigator/ Principal Investigator** | Dr Peter McEwen  Dr Kaushik Hazratwala  Dr Matthew Wilkinson |
| **Associate Investigator(s)** | Dr Ryan Faruque  Andrea Grant |
| **Location** | Mater Health Services North Queensland Ltd |

**Part 1 What does my participation involve?**

**1 Introduction**

This Participant Information Statement tells you about the research study, explaining the tests and treatments involved so you can make an informed decision about whether or not you want to take part in the research.

Participation in this research is voluntary. You will receive the best possible care whether or not you are involved in the study.

If you decide you do want to take part in the research study, you will be asked to sign the consent section attached. By signing it you are telling us that you:

• Understand what you have read

• Consent to take part in the research project

• Consent to have the tests and treatments that are described

• Consent to the use of your personal and health information as described.

**2 Background and aim of the research study**

If you have been invited to participate in this study it means you have significant osteoarthritis in both your knees and are planning to are planning to have them both replaced at the during the same surgery.

Kneeling is a very important function of the knee, and we know that many patients have difficulty with kneeling not only before their knee replacement, but after it as well. This is due to the skin incision that is classically performed as a midline incision over the centre of the kneecap. This poses two potential problems with kneeling:

1. The skin over the bony part that contacts the ground has a different feeling which can make kneeling uncomfortable.
2. The skin on the outside of the incision can have reduced feeling and this can be uncomfortable

This study aims to investigate whether a lateral skin incision improves the ability to kneel when compared to traditional midline incisions.

**3 What does participation in this research involve?**

Your surgeon will take a medical history from you and determine if you are eligible for the study. If you are, then he will explain the study to you and ask if you wish to participate. If you decide to participate in the research, during your surgery you will have one knee randomly selected to have an incision made on the outer side of the knee and the other knee will have a traditional midline incision. (*See image 1 below*). This study is randomised and prospective to make it scientifically powerful.



*Image 1 – in the image we can see the knee on the right has the traditional incision made in the midline of the knee cap. The knee on the left has the lateral incision, or incision located more to the outside of the knee.*

Consent

We will ask for your consent verbally and electronically to participate in the study. Consent will be obtained prior to any study assessments and procedures. We will ask you to provide consent to participate in research and agree to the Terms and Conditions of accessing FORCE THERAPEUTICS.

What is FORCE THERAPEUTICS?

FORCE THERAPEUTICS is a web-based database where your information will be confidentially stored. You will become familiar with accessing this database to keep in touch with your surgical care team, but also to complete patient assessment questionnaires following your surgery. Please ensure you complete these either in clinic as part of your routine assessment or online through your FORCE THERAPEUTICS profile.

Visits to your doctor after before and after surgery

At time-points after surgery we will ask you to come visit us for routine follow up of how you have been progressing after your knee replacement. During those visits we will also be looking at how much area of sensation loss has occurred to the outer area of skin as well as how well you can kneel onto the floor. Do not worry, we will only see how well you can kneel down and then get back up, but we do not expect you kneel down completely if this becomes too uncomfortable for you during the assessment. (See image 2: Kneeling Grading Method below for more details). If you have any concerns after your surgery, please do not hesitate to contact the care team via the FORCE THERAPEUTICS application or by phone call to your surgeon’s office.

Please see table below for an outline of pre-surgical assessments required as part of the study protocol.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | **Study Visits** | | | | |
|  | Pre-Surgery | Surgery | 6 weeks | 6 months | 12 months |
| Informed Consent/clinical exam | x | TKR | x | x | x |
| PROMS | x |  | x | x |
| Clinical assessment (Kneeling and Sensation) | x |  | x | x |

During Surgery:

The surgery to your knees will be done according to your randomization group, one knee will have the incision performed in the classical midline position, the other will have the incision made to the outside of the knee (lateral incision). Modern anaesthetic, surgical and pain relief techniques will be used to ensure you have minimal pain after surgery.

Post-Surgery:

You will need to attend your study doctor’s clinic for follow up appointments, please refer to the study visits log below.

How well do you kneel?

Kneeling is a complex series of movements and we would like to see how far down you can reach on each knee following these movement and then getting back up from them.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Grade | | | | |
| 1 | 2 | 3 | 4 | 5 |
|  |  |  |  |  |
| Partial Squat | Full Squat | Split Kneel | 90° Kneel | Full Kneel |

*Image 2:* Kneeling Grading Method

What does your knee feel like and look like?

After surgery we will test what your knee feels like on the outside of where the skin cut was made. We will ask you to tell us how it feels. We will measure the length of the incision scars.

How has your knee been progressing?

After your surgery you will come to visit your surgeon at several time points as outlined above. At those visits you will be asked to answer some questionnaires regarding how you feel about your knee and how its function has been progressing since the surgery.

Costs:

There are no costs associated with participating in this research project.

**4 Other information about the research study**

We aim to recruit a total of 33 patients in the study which will be conducted at the Mater Health Service North Queensland Ltd between September 2016 and September 2018.

**5 Do I have to take part in this research study?**

Participation in any research study is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the study at any stage. Your decision on whether or not to take part, or to take part and then withdraw, will not affect your routine treatment or your relationship with those treating you. You may wish to continue to use FORCE THERAPEUTICS as part of your continuation of care if you decide to not continue in a research project.

**6 What are the possible benefits of taking part?**

There is the potential for one of the knees to have a reduced loss in sensation and potentially improved kneeling ability in the same knee. The other knee will have no added benefit.

**7 What are the possible risks and disadvantages of taking part?**

The major disadvantage is that there will be visual asymmetry in your knees. That is, one scar will definitely look different to the other. The lateral incision scar is curved to the outside of the knee and is usually longer than the traditional midline incision scar (See image 3 below). If these disadvantages particularly concerns you than it would be best not to participate in this study.



Image 3: using two different incisions will leave the two scars on the knees definitely looking different

**8 Possible side effects from X-rays**

This research study involves exposure to a small amount of radiation. This exposure however is no greater than the standard post-operative management according to surgical protocol, thus does not put you at an increased risk of side effects.

**10 Can I have other treatments during this research project?**

Whilst you are participating in this research project, you may not be able to take some or all of the medications or treatments you have been taking for your condition or for other reasons. It is important to tell your study doctor and the study staff about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments. You should also tell your study doctor about any changes to these during your participation in the research project. Your study doctor should also explain to you which treatments or medications need to be stopped for the time you are involved in the research project.

**11 What if I withdraw from this research project?**

If you decide to withdraw from the project, please notify a member of the research team before you withdraw. This notice will allow that person or the research supervisor to discuss any health risks or special requirements linked to withdrawing.

**12 Could this research project be stopped unexpectedly?**

This research project may be stopped unexpectedly for a variety of reasons. These may include reasons such as:

* Unacceptable side effects
* Decisions made in the commercial interests of the sponsor or by local regulatory/health authorities.

**Part 2 Frequently asked questions**

**1 What will happen to information about me?**

By providing consent to the study doctor and relevant research staff, you consent to collection and use of personal health information for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. The data collected from this project will be stored on the password protected ORIQL Database’s and may be pooled (de-identified) for further retrospective research projects (following HREC approval). In such instances you will not be contacted to obtain permission for de-identified data to be used.

Information about you may be obtained from your health records held confidentially at this and other health services for the purpose of this research. By signing the consent form you agree to the study team accessing health records for the purpose of verifying the procedures and the data relevant to this Participant Information Sheet.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission. Information about your participation in this research project may be recorded in your health records.

You have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected.

**2 Complaints and compensation**

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment.

**3 Who is organising and funding the research?**

This research project is being funded by ORIQL. ORIQL researchers do not receive a personal financial benefit from your involvement in this research project.

**4 Who has reviewed the research project?**

This research project has undergone Human Research Ethics Committee (HREC) review. The ethical aspects of this research project have been approved by the HREC of Mater Health Services North Queensland Ltd.

**5 Further information and who to contact**

Project or medical problems that may be related to your involvement in the project you can contact the principal study doctor or your care team through FORCE THERAPEUTICS.

**Clinical contact person**

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| Name | *Andrea Grant* |
| Position | *Research Coordinator* |
| Telephone | *0413 685 331* |
| Email | *Research\_coordinator@oriql.com.au* |

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

**Complaints contact person**

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| Name | *Karen Gerrard* |
| Position | *Executive Director of Nursing* |
| Telephone | *07 4727 4444* |
| Email | *Karen.Gerrard@matertsv.org.au* |

For more information on participating in clinical trials you can consult the Australian Clinical Trials website: [www.australianclinicaltrials.gov.au](http://www.australianclinicaltrials.gov.au) The website was developed by the National Health and Medical Research Council (NHMRC) and the Department of Industry and Science which provides general information about clinical trials for consumers, health care providers, researchers and industry.