Participant Information Sheet

Intraosseous Regional Administration of Diclofenac (IRAD) in Primary Total Knee Arthroplasty for Postoperative Pain Management

Lead [Researcher / Study Doctor]: Simon W Young

Study Site: Southern Cross North Harbour

Contact phone number:

Ethics committee ref.:

You are invited to take part in a study investigating the effectiveness of a novel technique used with the aim of providing improved pain relief following your total knee joint replacement. Whether or not you take part is your choice. If you don't want to take part, you don't have to give a reason, and it won't affect the care you receive. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

This Participant Information Sheet will help you decide if you'd like to take part. It sets out why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what would happen after the study ends. We will go through this information with you and answer any questions you may have. You do not have to decide today whether or not you will participate in this study. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this.

If you agree to take part in this study, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep.

This document is 7 pages long. Please make sure you have read and understood all the pages.

Voluntary Participation and Withdrawal From This Study

Participation in this study is completely voluntary, and you are free to decline or participate as you wish. If you choose to participate, you may withdraw from the research at any practicable time. Declining or withdrawing from the study at any stage will not compromise your medical care in any way or form.

What is the purpose of the study?

Total knee joint replacements are often associated with significant pain post procedure, and it is within the surgeon's best interests to minimise postoperative pain to improve patient outcomes. The research team is conducting this study to investigate a novel technique known as intraosseous regional administration of analgesia (IORA), and the effectiveness of Diclofenac (Voltaren™) using this technique. Diclofenac is a non-steroidal anti-inflammatory similar to Ibuprofen. This method involves directly injecting pain medication directly into the shin bone after inflating a tourniquet around the thigh, to keep the medication localised in the surgical area.

The aim of this study is to demonstrate that this novel technique can provide superior pain relief/prevention compared to traditional methods, as well as provide improved post-operative outcomes for patients. Findings from this study will contribute to improvements in routine practice for total knee joint replacements, to provide improved pain relief and therefore better outcomes for future knee joint replacement patients.

How is the study designed?

This study will have 46 patients taking part in it, all will be total knee joint replacement patients from Southern Cross North Harbour. Each patient will be asked to participate in the trial from the time of surgical consent to the six week post-op clinic follow up appointment. As with routine total knee joint replacements, patient's will need to stay in hospital for the first few days following their surgery.

Participants who have consented to be part of the study will be randomised into two groups who will receive the following medication during their surgery:

- Group 1 (intervention group): 75mg Diclofenac (Voltaren™) injected into the bone (IORA) preoperatively.
- Group 2 (comparison group): An intravenous infusion of 75 mg Diclofenac (Voltaren™) preoperatively (control group)

Patients will have an equal chance of being in each study arm, but will be blinded to which group they are in (so will be unaware of which intervention they have received).

This study will closely monitor each participant's pain levels following surgery, and review the amount of additional pain relief (in particular opioids) that patients require to manage their pain. Adverse effects to the medication will be closely monitored by Hospital Staff. Participants will be required to fill out Pain Diaries and questionnaires/surveys to assess the effects of the different modes of pain relief investigated.

Who can take part in the study?

You have been chosen to participate in this study as you are planning to have a primary total knee joint replacement for Osteoarthritis, and fall within the acceptable age range for this study (between 18 and 80 years old).

It is important to note however, you may not be eligible for this study if for any reason you are unable to take Diclofenac (Voltaren™). This includes known allergy or hypersensitivity to either of the medications, or drugs of the same type. Patients with severe kidney, liver, or heart failure will also be unable to participate.

If you are found to be overly sensitive to pain (based on a questionnaire), you will not be able to participate as this may skew the results.

Investigators will screen patients against inclusion and exclusion criteria to ensure patients are suitable to take part in the study. This is in the best interests for your safety as our patient.

What will my participation in the study involve?

Baseline information will need to be obtained prior to the operation, including demographic information, and participants will be required to complete multiple baseline surveys which relate to chronic pain and "knee health".

Following the operation, participants will be asked to record their pain levels, the amount of extra pain relief they are using, as well as how pain has affected their walking ability and sleep, at certain time intervals, in a Pain Diary provided to them. This will be for one week following surgery, and we ask for participants to be diligent in filling the Pain Diary in a timely manner according to the time intervals. This will all be explained and set out clearly for participants

A postoperative recovery questionnaire will also need to be completed the day after the operation.

Further postoperative surveys will need to be filled out by participants at their two week and six week clinic follow-up, and the Pain Diary will be handed in at the two week clinic.

What are the possible risks of this study?

Foreseeable risks of the study include adverse effects of the study medications being administered, i.e. Diclofenac (Voltaren™).

- Common adverse effects of Diclofenac (Voltaren™) may include nausea, vomiting, diarrhoea, abdominal pain. More severe (but rare) adverse effects include gastrointestinal bleeding, anaphylaxis, heart attack, and stroke.

Many patients will experience no adverse effects from these medications despite some labeled as "common", and many can be minimised with medication to alleviate these symptoms.

Complications from the process of administering the medication into bone (intraosseous injection) may also arise, but this technique is already part of the surgeon's routine surgical practice and complications are rare. These may include:

- Fracturing bone
- Infection (very rare)
- Misplacement of the needle leading to fluid being introduced elsewhere in the leg
- Compartment syndrome (very rare) caused by increased pressures within the leg tissue from large volumes of fluid being infused into it.

ALL adverse effects will be closely monitored by Hospital Staff and will be managed as appropriate to alleviate these symptoms where possible, and patients will receive treatment if required. Any new information about adverse effects related to the study that become available during the study will be discussed with participants.

What are the possible benefits of this study?

Possible direct benefits for participants in this study includes reduced pain following their total knee joint replacement, thus leading to improved recovery and likely better patient outcomes.

Possible indirect benefits of this study include potential changes to routine total knee joint replacement surgical procedure to provide better post-op pain relief, and better outcomes in future patients. This study could also pave the way for further studies to investigate administering other medications using the same technique.

What are the alternatives to taking part?

If participants choose not to take part, they will undergo routine total knee joint replacements which still involve having an injection of Diclofenac (Voltaren™) into the bone for pain management.

Will any costs be reimbursed?

Participants will not incur any costs in this study.

What if something goes wrong?

If you were injured in this study, you would be eligible **to apply** for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will

automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.

If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won't affect your cover.

What will happen to my information?

During this study the study doctors/researchers, nurses and other Southern Cross North Harbour staff will record information about you and your study participation. This includes the results of any study assessments (as mentioned prior). If needed, information from your hospital records and your GP may also be collected. You cannot take part in this study if you do not consent to the collection of this information.

Identifiable Information

Identifiable information is any data that could identify you (e.g. your name, date of birth, or address). The following groups may have access to your identifiable information:

- Researchers
- Southern Cross North Harbour staff (to complete study assessments)
- Ethics committees, or government agencies from New Zealand or overseas, if the study or site is audited. Audits are done to make sure that participants are protected, the study is run properly, and the data collected is correct.
- Your usual doctor, if a study test gives an unexpected result that could be important for your health. This allows appropriate follow-up to be arranged.
- Rarely, it may be necessary for the Study Doctor to share your information with other people – for example, if there is a serious threat to public health or safety, or to the life or health of you or another person OR if the information is required in certain legal situations.

De-identified (Coded) Information

To make sure your personal information is kept confidential, information that identifies you will not be included in any report generated by researchers. Instead, you will be identified by a code. A list will be kept linking your code with your name, so that you can be identified by your coded data if needed.

The following groups may have access to your coded information:

- Researchers and trained study staff
- Ethics committees, or government agencies from New Zealand or overseas

The results of the study may be published or presented, but not in a form that would reasonably be expected to identify you.

Future Research Using Your Information.

Your coded information may be used for future research related to intraosseous regional analgesia for reducing postoperative pain. Your coded information may also be used for other medical and/or scientific research that is unrelated to the current study.

This future research may be conducted overseas. You will not be told when future research is undertaken using your information. Your information may be shared widely with other researchers or companies. Your information may also be added to information from other studies, to form much larger sets of data.

You will not get reports or other information about any / some research that is done using your information.

Your information may be used indefinitely for future research unless you withdraw your consent. However, it may be extremely difficult or impossible to access your information, or withdraw consent for its use, once your information has been shared for future research.

Security and Storage of Your Information.

Your identifiable information is held at Southern Cross North Harbour during the study. After the study it is transferred to a secure archiving site and stored for at least 15 years, then destroyed. Your coded information will be entered into electronic case report forms and sent through a secure server to the sponsor. Coded study information will be kept by the sponsor in secure, cloud-based storage indefinitely. All storage will comply with local and/or international data security guidelines.

The linked data in this study will be destroyed in 15 years along with the rest of the data.

Risks.

Although efforts will be made to protect your privacy, absolute confidentiality of your information cannot be guaranteed. Even with coded and anonymised information, there is no guarantee that you cannot be identified. The risk of people accessing and misusing your information (e.g. making it harder for you to get or keep a job or health insurance) is currently very small, but may increase in the future as people find new ways of tracing information.

Data-linking can produce a detailed picture of individuals. Data-linking increases the risk of identifying individuals and possibly others who may be in the same households, organisations, iwi or hapū. Some of the data sets being linked may have been designed, and some data may have been collected, without the intention of them being used with other data sets. Some data sets may have been collected in ways which have resulted in biases, meaning that there is the potential for inappropriate inferences to be drawn. These things have the potential to cause harm. While we have taken steps to minimise their likelihood, we cannot guarantee they will not occur.

Maori Data Sovereignty

During the study, data may be collected from participants identifying as Maori. Personal and health information is a tāonga (treasure) and will be treated accordingly.

Formal Māori consultation for this study will be completed as part of the Locality Approval Process for New Zealand study site(s). Any recommendations for additional measures to improve Māori rights and interests in relation to data will be acted upon.

Rights to Access Your Information.

You have the right to request access to your information held by the research team. You also have the right to request that any information you disagree with is corrected.

Please ask if you would like to access the results of your screening and safety tests during the study. You may access other study-specific information before the study is over, but this could result in you being withdrawn from the study to protect the study's scientific integrity.

If you have any questions about the collection and use of information about you, you should ask the researcher/study doctor.

Rights to Withdraw Your Information.

You may withdraw your consent for the collection and use of your information at any time, by informing your Study Doctor.

If you withdraw your consent, your study participation will end, and the study team will stop collecting information from you.

Information collected up until your withdrawal from the study will continue to be used and included in the study. This is to protect the quality of the study.

Data-Linking.

In this study we will be linking your study information with other data sets which include information about you. This is called 'data-linking'. Data-linking in this study is mandatory.

In this study participant medical records will only be used to obtain demographic data (e.g. age, gender, ethnicity, BMI) and previous medical history (e.g. comorbidities, previous surgical history in the knee joint) that is relevant to the study question. A list of identifiable NHIs will be stored in a password-protected file on a secure computer.

What happens after the study or if I change my mind?

Participants should inform their surgeon or a member of the research team should they wish to withdraw from the study. Withdrawing will not affect their medical care and participants have no obligation to state their reasoning. Should a participant withdraw, no further data will be collected from them by study staff, however data collected prior to the participant's withdrawal will continue to be used and analysed. Patients may be able to be told which treatment they received after the conclusion of the study.

Can I find out the results of the study?

Participants have the right to request study results, and if requested for, will be provided with a plain English summary after publishing.

Who is funding the study?

Funding will be provided by The Wishbone Orthopaedic Research Foundation, supported by the New Zealand Orthopaedic Association

Who Has Approved the study?

This study has been approved by an independent group of people called a Health and Disability Ethics Committee (HDEC), who check that studies meet established ethical standards. The [insert Committee name] has approved this study.

Who do I contact for more information or if I have concerns?

If you have any questions, concerns or complaints about the study at any stage, you can contact:

Simon Young
Orthopaedic Surgeon
Southern Cross Hospital North Harbour
232 Wairau Road
Glenfield
Auckland 0627
09 925 4400

If you want to talk to someone who isn't involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050
Fax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@advocacy.org.nz
Website: https://www.advocacy.org.nz/

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

Phone: 0800 4 ETHIC
Email: hdecs@health.govt.nz

Orthopaedic Surgery
Southern Cross North Harbour
P.O. Box 101-488
North Shore Mail Centre,
Auckland City, 0745
Telephone: (09) 925 4400
Facsimile: (09) 925 4434

Consent Form

Intraosseous Regional Analgesia: A Novel Technique for Postoperative Pain Prevention in Primary Total Knee Replacements

Project Title: Intraosseous Regional Analgesia in Primary Total Knee Arthroplasty: Comparing the Analgesic Efficacy of Intraosseous Regional Diclofenac-Morphine, Intraosseous Regional Diclofenac, and Systemic Diclofenac for Postoperative Pain Management

If you need an interpreter, please tell us and one can be made available.

- I have read or have had read to me in my first language, and I understand the Participant Information Sheet.
- I acknowledge that the nature, purpose, risks and alternative treatments have been fully explained to my satisfaction and I have had the opportunity to ask questions. I am satisfied with the answers I have been given.
- I have had the opportunity to use whānau support or a friend to help me ask questions and understand the study.
- I understand that taking part in this study is voluntary (my choice), and that I may withdraw from the study at any time, and this will in no way affect my future health care at Southern Cross North Harbour.
- If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed.
- I understand that my participation in this study is confidential and that no material that could identify me will be used in any reports on this study.
- I understand that research staff will be collecting and processing my information, including information about my health.
- I agree to an approved auditor appointed by the New Zealand Health and Disability Ethics Committees, or any relevant regulatory authority or their approved representative reviewing my relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study.
- I consent to my GP or current provider being informed about my participation in the study and of any significant abnormal results obtained during the study Yes ☐ No ☐
- I understand the compensation provisions for this study.

- I have had time to consider whether to take part in the study.
- I know whom to contact if I have any side effects from the study, or if I have any questions about the procedures used in this study or about the study in general.
- I wish to receive a summary of the study results (please tick one): Yes ☐ No ☐

I hereby voluntarily consent to my involvement in the research project named above.

Name (please print): .

Signature: **Date:**

Name of person who conducted informed consent discussion (please print):

Signature: **Date:**