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| Participant Information Sheet **Intraosseous Regional Administration of Diclofenac in Anterior Cruciate Ligament Reconstruction** | | |
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| Lead Researcher: Simon Young  Study Site:  North Shore Surgical Centre Southern Cross Hospital North Harbour  Contact phone number:  Ethics committee ref.: |  |  |
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You are invited to take part in a study on investigating a new technique in administering diclofenac to improve pain management in anterior cruciate ligament (ACL) reconstructions. 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 11 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

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| **Voluntary Participation and Withdrawal From This Study** |

Participation in this study is entirely voluntary. You are free to choose whether or not to take part, and you can also change your mind at any time. If you decide to withdraw from the study, you can do so without giving a reason, and there will be no negative consequences for you. Your decision to participate or not will not negatively affect your medical care in any way.

## What is the purpose of the study?

Anterior cruciate ligament (ACL) injuries involve damage to a major ligament in the knee, which can cause pain, swelling, and instability. ACL reconstruction surgery is a common treatment to repair the damaged ligament, but managing pain after the surgery can be challenging.

The purpose of this study is to compare different methods of administering diclofenac (also known as ’Voltaren’, an anti-inflammatory medication similar to ibuprofen) to find out which methods work best for people recovering from ACL reconstruction. Participants will either receive diclofenac intravenously (through a vein) or intraosseously (through bone). By understanding which pain management strategies are most effective, this research aims to improve recovery and provide better care for patients. The findings could benefit communities by helping doctors offer safer and more effective pain relief, leading to quicker recovery and improved quality of life for patients.

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| **How is the study designed?** |

This study will include approximately 60 participants in total. Participation in the study will last around 8 weeks, involve checks at your usual post operative clinic, as well as filling out a log book at home to track levels of pain and pain medication consumption. It is expected that you will be able to go home on the day of the surgery, being in the study will not require any more time in hospital or clinic visits than normal.

For those taking part in the study, the treatment will involve either receiving 75mg diclofenac intravenously or intraosseously. This medication will be given whilst you are under anaesthesia so you should feel no pain at the time of administration. Participants will be randomly assigned to one of the study groups, with a 1 in 2 chance of receiving each type of treatment. Randomization means that the treatment is chosen by chance, like flipping a coin, to make sure the groups are balanced and the results are fair.

Participants will be blinded (unaware) to which study group they will be in.

Throughout the study, we will conduct assessments to monitor your pain and understand the effects of the treatment. This will include questionnaires to assess your pain and knee function, a diary record of your pain relief medication use, and clinic visits to assess the function and movement of your knee.

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| **Who can take part in the study?** |

You have been chosen to participate in this study because you are scheduled to undergo ACL reconstruction surgery.

To take part, you must meet certain criteria. You need to be at least 18 years of age and be generally healthy apart from your knee injury. You cannot participate if you have certain medical conditions (including significant kidney, liver, and heart disease), are pregnant, or have a history of allergic or severe adverse reactions to the treatments used in the study. Furthermore, if you have any concomitant knee injuries, are intolerant to surgery/anaesthesia, poorly controlled mental health, or have significant use of pain relief prior to the procedure, you will not be able to participate. This helps us ensure the safety and accuracy of the study.

## What will my participation in the study involve?

Your participation in the study will involve several steps to help us understand how different pain management options work after ACL reconstruction surgery.

1. **Initial Assessment**: Prior to your surgical procedure, you will begin with an initial visit where we’ll explain the study in detail and answer any questions you might have. You’ll also provide consent to participate. We’ll review your medical history and conduct a physical examination to ensure you’re eligible for the study. You’ll also complete a questionnaire to assess your current anxiety levels associated with your knee injury as well as your current pain and pain medications you are taking
2. **Day of the Surgical Procedure**: You will come into hospital and will receive the same presurgical process all individuals receive regardless of study participation. You will then receive your surgical procedure and following this procedure, participants will record their pain levels and pain relief medication intake. It is anticipated that you will be able to go home on the day of the procedure.
3. **At Home:** Throughout the study, you will complete a series of questionnaires within a diary we provide. These will ask about your pain levels, pain relief usage, and functional outcome. Entries into this diary occurs twice daily, once in the morning, and once in the evening, in total taking up no longer than a couple minutes each day. Making entries into the diary will be the main difference between participating and not participating in the study as the standard of care does not include such diary entry requirements.
4. **Clinic Follow-up Visits**: You will also be asked to return to hospital for 2 clinic follow-ups to assess the mobility of your knee. Each visit may take around 15 minutes. Having 2 clinic appointments is the standard of care and participation in the study will not require any additional visits.

### Summary of Assessments

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| Visit Type | Type of Assessment | Expected Duration |
| Initial Assessment | Initial assessment and consent | 15 minutes |
| Day of Surgical Procedure | Pain level and pain medication recording | Every hour for 3 hours following operation and every subsequent hour till discharge |
| At Home | Pain level and pain medication recording | First 2 weeks |
| Clinic Follow-up Visits | Questionnaires and knee mobility examination | 15 minutes |

Overall, your participation will help us gather important information to improve pain management strategies for future patients.

As one of the surveys in the study measures anxiety related related to movement, if a participant's responses indicate severe distress, the study team will promptly follow up. A trained member of the research team will reach out to the participant within 24 hours to assess their well-being and provide support. If needed, the participant will be referred to appropriate mental health services for further assistance. In cases of immediate concern, the team will connect the participant with the crisis team to ensure their safety and well-being. The study team will handle all findings sensitively and confidentially, prioritising the participant's mental health needs.

## 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 side 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.

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| **What are the possible benefits of this study?** |

There are several potential benefits to participating in this study:

1. **Direct Benefits**: You may experience improved pain management during your recovery from ACL reconstruction surgery. By comparing different pain relief administration options, we aim to identify the most effective methods, which could lead to better pain control and a smoother recovery process for you.
2. **Indirect Benefits**: The findings from this study may help future patients undergoing ACL surgery. By understanding which pain management strategies work best, we can improve overall care practices, leading to enhanced recovery experiences for others in similar situations. Additionally, the study may contribute to broader knowledge in the field of pain management, benefiting healthcare providers and patients alike.

Overall, while individual results may vary, your participation could play a valuable role in advancing pain management strategies and improving outcomes for future patients.

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| **What are the alternatives to taking part?** |

If you choose not to participate in this study, you will be offered the current standard of care - which is receiving diclofenac intraosseously whilst you are in surgery.

## Will any costs be reimbursed?

Participation in this study will not incur any costs to participants.

## 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 hospital staff will record information about you and your study participation. This includes the results of any study assessments. 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
* 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 the researcher. Instead, you will be identified by a code. The researcher will keep a list 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 administration or 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 North Shore Surgical Centre or Southern Cross North Harbour during the study. After the study it is transferred to a secure archiving site and stored for at least 10 years, then destroyed. All storage will comply with local and/or international data security guidelines.

The linked data in this study will be destroyed in 10 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.

Māori Data Sovereignty

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

Formal Māori consultation for this study has been completed through He Kamaka Waiora Health New Zealand Waitematā and Auckland research committee. 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.

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, 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?**

If you decide you want to withdraw from the study at any point, please inform the research team or your healthcare provider as soon as possible. You can do this during any visit or by contacting us directly using the information provided in the study materials.

If you choose to withdraw, any data collected up to that point will be used for research purposes unless you request otherwise. You will have the option to have your data removed from the study if you wish.

You will not know which treatment you received until the study is completed. At that time, we will inform you of the treatment you were given, if you wish to know.

Your decision to withdraw or continue participating will not affect your standard medical care or any future treatment options.

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| **Can i find out the results of the study?** |

Yes, you can find out the results of the study. If you request it, we will provide you with a summary of the findings once the study is completed.

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| **Who is funding the study?** |

There is no funding for this study as of writing of this information sheet. In the future when funding is secured, should you wish to be informed of this, please contact us on the details provided in this information sheet.

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| **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

North Shore Surgical Centre

213 Shakespeare Road

Takapuna

Auckland 0620

09 953 9300

[enquiries@nssurgical.co.nz](mailto:enquiries@nssurgical.co.nz)

Or

Southern Cross Hospital North Harbour

232 Wairau Road

Glenfield

Auckland 0627

09 925 4400

[northharbour@southerncrosshospitals.co.nz](mailto:northharbour@southerncrosshospitals.co.nz)

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](mailto: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](mailto:hdecs@health.govt.nz)

For Māori health support please contact: He Kamaka Waiora

Telephone number 09 486 8900 ext: 43204

Email [hkwresearch@waitematadhb.govt.nz](mailto:hkwresearch@waitematadhb.govt.nz)

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| Consent Form **Intraosseous Regional Administration of Diclofenac in Anterior Cruciate Ligament Reconstruction** |  |

**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 whậnau 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 North Shore Surgical Centre or 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 (please tick one):   
    
  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

**Declaration by participant:**

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

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| Participant’s name: | |
| Signature: | Date: |

**Declaration by member of research team:**

I have given a verbal explanation of the research project to the participant, and have answered the participant’s questions about it.

I believe that the participant understands the study and has given informed consent to participate.

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| Researcher’s name: | |
| Signature: | Date: |