Participant Information Sheet/Consent Form

Interventional Study - *Adult providing own consent*

Repatriation General Hospital

Title	Obturator Posterior and Adductor Canal blocks vs Femoral Nerve block for Anterior Cruciate Ligament reconstruction
Coordinating Principal Investigator/ Principal Investigator	Dr Perry Fabian
Associate Investigator(s)	Dr Jason Koerber Dr Shannon Sim Vijeyadezmi Ganasan Brad Harvey
Location	Repatriation General Hospital Noarlunga Health Service

Part 1 What does my participation involve?

Nerve blocks are frequently used together with your general anaesthetic for your ACL reconstruction surgery because your knee may be quite painful afterwards.

A nerve block will help to reduce this pain and also help to reduce potential side effects of the (opioid) medicines taken to treat this pain (eg nausea and vomiting)

Femoral nerve blocks are effective nerve blocks to reduce pain but may cause thigh muscle weakness. This weakness can INITIALLY limit standing and walking

An alternative to femoral nerve block is combined adductor canal and obturator posterior branch nerve block. This can potentially produce good pain relief with little to no muscle weakness.

1 Introduction

You are invited to take part in this research project. The research project is testing an alternative analgesic treatment for ACL reconstruction surgery. The new treatment is called a Combined Obturator Posterior and Adductor Canal block.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and treatments involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local doctor.

Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the research project, you will be asked to sign the consent section. 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.

You will be given a copy of this Participant Information and Consent Form to keep.

2 What is the purpose of this research?

Nerve blocks are frequently used together with your general anaesthetic for your ACL reconstruction surgery because your knee may be quite painful afterwards.

A nerve block will help to reduce this pain and also help to reduce potential side effects of the (opioid) medicines taken to treat this pain (eg nausea and vomiting).

The effects of nerve blocks generally last for between 8 and 24 hours.

Femoral nerve blocks are effective nerve blocks to reduce pain but may cause thigh muscle weakness. This weakness can INITIALLY limit standing and walking. It may also result in a longer stay in hospital.

An alternative to femoral nerve block is combined adductor canal and obturator posterior branch nerve block. This can potentially produce good pain relief with little to no muscle weakness. This block is established to be safe and effective for knee replacement surgery. We want to see if it is also effective for ACL reconstruction surgery.

This research has been initiated by the study doctors, Dr Perry Fabian, Dr Jason Koerber and Dr Shannon Sim.

3 What does participation in this research involve?

All patients undergoing ACL reconstructive surgery will be screened for eligibility for enrolment into the study. If you are eligible and agree to be a part of the study, you will be randomly allocated to one of the two blocks. Both blocks are performed by depositing the same dose and amount of drug (15ml of 0.75% Ropivicaine, which is 112.5mg) next to nerves under direct ultrasound guidance. You will also receive a general anaesthetic, and so be asleep for the surgery. All patients will receive the same pain reducing medications, regularly and as needed.

You will receive standard anaesthetic and surgical care around the time of your operation. This will include a visit on the day following surgery by the Acute Pain Service, who will ask how comfortable you are, and assess for any complications of analgesia.

You will not be asked to do anything extra compared to patients who are not in the trial. The only requirement is that you speak with a member of the study team on the day following surgery to see how comfortable you are and if you have any leg weakness. Your leg muscle strength will also be assessed by asking you to raise your leg from the bed, or to hold it in the air after having it raised.

If you consent to joining this study, you are free to withdraw your consent at any time. Consent forms must be signed prior to any study assessment being performed. All information collected is anonymized (i.e. there will be nothing to identify you) and stored securely.

You will be participating in a randomised controlled research project. Sometimes we do not know which treatment is best for treating a condition. To find out we need to compare different treatments. We put people into groups and give each group a different treatment. The results are compared to see if one is better. To try to make sure the groups are the same, each participant is put into a group by chance (random). You have a one in two chance of being in each group.

You will be participating in a blind study and only your study doctor will know which of the treatments you are receiving.

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study doctors or participants jumping to conclusions.

There are no additional costs associated with participating in this research project, nor will you be paid. All medication, tests and medical care required as part of the research project will be provided to you free of charge.

4 What do I have to do?

You will not be asked to do anything extra compared to patients who are not in the trial. The only requirement is for a member of the study team to speak with you on the day following surgery to see how comfortable you are and if you have any leg weakness.

There are no lifestyle or dietary restrictions. You can continue to take your regular medications and are free to donate blood during the study period.

5 Other relevant information about the research project

This research project is being undertaken at the Repatriation General Hospital and at Noarlunga Health Service. The study group comprises five individuals: the three study doctors and two Flinders University medical students undertaking advanced studies in research. You will also receive standard medical care from the doctors and nurses at your hospital.

6 Do I have to take part in this research project?

Participation in any research project 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 project at any stage.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision to take part or not take part, or take part and then be withdrawn, will not affect the your routine treatment, your relationship with those treating them, or your relationship with your hospital.

7 What are the alternatives to participation?

You do not have to take part in this research project to receive treatment at this hospital. Other options are available. These include: femoral block with general anaesthesia, spinal anaesthesia, or general anaesthesia without regional block. Your study doctor will discuss these options with you before you decide whether or to take part in this research project. You can also discuss the options with your local doctor.

8 What are the possible benefits of taking part?

We cannot guarantee or promise that the participant will receive any benefits from this research; however, possible benefits may include equal or superior analgesia without thigh muscle weakness.

9 What are the possible risks and disadvantages of taking part?

Medical treatments often cause side effects. You may have none, some or all of the effects listed below, and they may be mild, moderate or severe. If you have any of these side effects, or you are worried about them, talk with the study doctor. Your study doctor will also be looking out for side effects.

There may be side effects that the researchers do not expect or do not know about and that may be serious. Tell your study doctor immediately about any new or unusual symptoms.

Many side effects go away shortly after treatment ends. However, sometimes side effects can be serious, long lasting or permanent. If a severe side effect or reaction occurs, the participant's study doctor may need to stop the participant's treatment. The participant's study doctor will discuss the best way of managing any side effects with you.

Side Effect	How often is it likely to occur?	How severe might it be?	How long might it last?
Prolonged block or areas of numbness, weakness or tingling	1 in 2500 blocks	Moderately severe	Days to Weeks
Permanent nerve damage	1 in 6666	Severe	Permanent
Injection of drug into blood vessel	1 in 1000	Severe	Minutes to Hours

Having a drug injected may cause some discomfort, bruising, minor infection or bleeding. If this happens, it can be easily treated.

These days, whilst anaesthesia is generally very safe there are some associated risks. The most common problems associated with anaesthesia are feeling nauseated or vomiting, bruising at the site of injections, sore throat or hoarse voice. Most people do not have these

problems. If these problems do happen, they usually get better very quickly. Damage to teeth may occur, but this is rare. The risk of brain damage or death due to anaesthesia is very rare.

The risk of problems from anaesthesia increases for patients who are having more major surgery, those with medical problems and those that require difficult anaesthetic procedures. If you have any concerns about these issues, you should discuss them with the study team.

10 What if new information arises during this research project?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, your study doctor will tell you about it and discuss with you whether you want to continue in the research project. If you decide to withdraw, your study doctor will make arrangements for your regular health care to continue. If you decide to continue in the research project you will be asked to sign an updated consent form.

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 further discuss any health risks or special requirements linked to withdrawing.

If you do withdraw during the research project, the study doctor and relevant study staff will not collect additional personal information you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected by the study staff up to the time you withdraw will form part of the research project results. If you do not want them to do this, you must tell them before you join the research project.

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
• The treatment being shown not to be effective
• The treatment being shown to work and not need further testing

13 What happens when the research project ends?

The project will take approximately two years to complete. Findings from the study will be presented at medical meetings and conferences, and may be published in a medical journal. If you wish, a summary of the results can be sent to you when the research project is completed.

Part 2 How is the research project being conducted?

14 What will happen to information about me?

By signing the consent form you consent to the study doctor and relevant research staff collecting and using personal information about you for the research project. Any information

obtained in connection with this research project that can identify you will remain confidential. Each participant will be allocated a number. This number will be used during data analysis. You will not be identifiable during analysis, but using this number will allow for you to be re-identified if required. All data will be stored in an encrypted Excel spread sheet on a USB drive. The USB drive will be stored in a locked cupboard securely in the office of the Flinders Medical Centre Anaesthetic Department. Only the study team will have access to it. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law. You are only being asked to provide consent for the use of the data for this project only.

Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

Information about you may be obtained from your health records held 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 if they are relevant to your participation in this research project. 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.

In accordance with relevant Australian and South Australian privacy and other relevant laws, 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. Please contact the study team member named at the end of this document if you would like to access your information.

Any information obtained for the purpose of this research project that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

15 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. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

16 Who is organising and funding the research?

This research project is being conducted by Perry Fabian, Jason Koerber and Shannon Sim.

17 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the Southern Adelaide Clinical Human Research Ethics Committee.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

Approval has been given by Dr Peter Lillie, Head of the Department of Anaesthetics at SALHN.

20 Further information and who to contact

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the principal study doctor on 8204 4266:

Clinical contact person

Name	Perry Fabian
Position	Consultant Anaesthetist
Telephone	8204 4266
Email	perry.fabian@sa.gov.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

Name	Paula Davies
Position	Manager, Office for Research
Telephone	8204 6061
Email	SALHNofficeforresearch@sa.gov.au

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Reviewing HREC name	Southern Adelaide Clinical Human Research Ethics Committee
HREC Executive Officer	Damian Creaser
Telephone	8204 6453
Email	SALHNofficeforresearch@sa.gov.au

Reviewing HREC approving this research and HREC Executive Officer details

Local HREC Office contact (Single Site -Research Governance Officer)

Name	Dawn Jennifer
Position	Research Governance Officer
Telephone	8204 6139
Email	SALHNofficeforresearch@sa.gov.au

Consent Form - *Adult providing own consent*

Title	Obturator Posterior and Adductor Canal blocks vs Femoral Nerve block for Anterior Cruciate Ligament reconstruction
Coordinating Principal Investigator/ Principal Investigator	Dr Perry Fabian
Associate Investigator(s)	Dr Jason Koerber Dr Shannon Sim
Location	Repatriation General Hospital

Declaration by Participant

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to Flinders Medical Centre concerning my disease and treatment for the purposes of this project. I understand that such information will remain confidential.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future health care.

I understand that I will be given a signed copy of this document to keep.

Name of Participant (please print) _____

Signature _____ Date _____

Name of Witness* to Participant's Signature (please print) _____

Signature _____ Date _____

* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Study Doctor/
Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

Form for Withdrawal of Participation - *Adult providing own consent*

It is recommended that this form NOT be included as part of the PICF itself, but that it be developed at the same time and made available to researchers for later use, if necessary. Note that a participant's decision to withdraw their separate consent to the use and storage of tissue will need to be documented separately and linked to the PICF used for that purpose.

Title	Obturator Posterior and Adductor Canal blocks vs Femoral Nerve block for Anterior Cruciate Ligament reconstruction
Coordinating Principal Investigator/ Principal Investigator	Dr Perry Fabian
Associate Investigator(s)	Dr Jason Koerber Dr Shannon Sim
Location	Repatriation General Hospital Noarlunga Health Service

Declaration by Participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with Repatriation General Hospital or Noarlunga Health Service.

Name of Participant (please print) _____

Signature _____ Date _____

In the event that the participant's decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will need to provide a description of the circumstances below.

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

Name of Study Doctor/
Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.