Participant Information Sheet

Interventional Study - *Adult providing own consent*

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Title	Sedation vs Axillary Brachial plexus block in Interventional Radiology (SABIR)
Short Title	SABIR
Protocol Number	2021/PID03679
Project Sponsor	None
Coordinating Principal Investigator	
Associate Investigators	
Location	

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project. This is because you are undergoing an endovascular fistula procedure with interventional radiology. The research project is evaluating a method of procedural pain relief called “axillary block” compared to intravenous sedation in Interventional Radiology.

This participant information sheet tells you about the research project, explaining the process 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 do not 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 sheet to keep for your own records.

2 What is the purpose of this research?

Endovascular fistula procedures (fistuloplasty) are a commonly performed procedure in the interventional radiology department. Although it is a minimally invasive procedure, it can be uncomfortable and therefore routinely requires intravenous sedation for pain relief. An alternative to intravenous sedation is axillary nerve block.

Axillary nerve block is a regional anaesthesia which temporarily numbs and paralyses the arm for the duration of the procedure. There has been research to suggest that this method of procedural pain relief has the benefit of reduced risk of over sedation compared to intravenous sedation, and can provide equal or better procedural anaesthesia. Axillary block is currently being used in operating theatres for arm procedures, as well as being commonly used in the Interventional Radiology department.

The purpose of this study is to determine whether use of axillary block for interventional radiology fistuloplasties provides better patient experience and procedural outcomes compared to intravenous sedation. This has already been shown in other procedures. We hope that showing the benefit of axillary block will lead to improved outcomes and patient experiences in the future.

This research is being conducted by the Liverpool Hospital Interventional Radiology Department.

This research has been initiated by the study doctor, Dr Ross Copping.

There is no funding or grant for this procedure.

There is no commercial sponsorship for the study.

3 What does participation in this research involve?

You will be assessed to see if you meet the inclusion criteria for this project. If deemed eligible, a consent form and thorough discussion will occur regarding the project, and what is involved. At the time of enrolment into the study, you will be asked some questions regarding your general health and function, your fistula history, as well as pre-procedural pain levels.

You will be participating in a prospective non-randomised controlled research project. To confirm effectiveness of this anaesthetic axillary block) in the interventional radiology fistuloplasty setting, we need to compare this anaesthesia with the current standard of practice: intravenous sedation.

Participants will be allocated into one of two study groups. One group will receive axillary block; the other group will receive intravenous sedation. We will closely monitor the experience between these 2 groups, including levels of pain during intervention, and compare to see if axillary block is of benefit. Participants are allocated to one of these 2 groups based on proceduralist preference or patient preference. This study is a non-blinded study. This means that you and the study doctor and nurses will be aware of which form of pain relief you are receiving at the time of the procedure.

Throughout the procedure, you will be asked regarding your pain and anxiety levels at regular intervals. After the procedure you will be interviewed prior to discharge home regarding your experience with the procedure and anaesthesia you received.

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way.

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?

There are no restrictions in participating in this study. You will be monitored in the interventional radiology department for a minimum of one hour post procedure as is routine to ensure you are well. You should follow the post procedure instructions provided which may vary depending on the individual procedure.

5 Other relevant information about the research project

This project will have two different groups – those receiving the axillary block for procedural pain relief and those receiving intravenous sedation.

For this study we will be aiming to recruit 50 participants over the duration of the data collection period. This study is being run at a single site; in the Liverpool Hospital Interventional Radiology department.

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 without compromising your treatment in any way.

If you do decide to take part, you will be given a consent form to sign and you will be given a copy of this sheet to keep for your own records.

Your decision whether or not to take part or to take part and then withdraw, will not affect your planned treatment, your relationship with your treating team or your relationship with Liverpool 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. There are other options available, including receiving the same treatment under intravenous sedation or axillary block if you do not participate in the study.

Your study doctor will discuss these options with you before you decide whether or not 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 you will receive any benefits from this research; however, possible benefits may include reduced pain and anxiety for you during the procedure (and possibly other patients going through the same procedure in the future).

Potential benefits include the possibility of better pain relief during procedure. If axillary block is of benefit, this will help make patients more comfortable for fistuloplasty procedures in the future.

Other benefits may include more timely procedure, as performing an axillary block requires less staffing resources than intravenous sedation.

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

Medical treatments often cause side effects. Generally, axillary block is safe. You may have none, some or all of the effects listed below, and they can range from mild to moderate or severe. If you are concerned or experience any of these side effects, please talk with your study doctor. Your study doctor will closely monitor for any potential side effects. There may be side-effects that the researchers do not expect or do not know about which can be serious. Please tell your study doctor immediately about any new or unusual symptoms that you experience.

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, your study doctor may need to stop your treatment. Your study doctor will discuss the best way of managing any side effects with you.

Risks for axillary block below:

Common side effects and complications include:
• pain at the injection site
• bruising (haematoma) at the injection site: if you take blood thinning medicines you are more likely to get a haematoma as it may affect your blood clotting.

Uncommon side effects and complications include:
• failure of block: this may require a further injection of anaesthetic or a different method of anaesthesia to be used
• temporary nerve damage recovering in a few days to months, damage may cause weakness and/or numbness of the body part that the nerve goes to
• overdose of local anaesthetic
• allergic reaction
• lung collapse
• damage to surrounding structures such as blood vessels, nerves and muscles.

Rare risks and complications include:
• permanent nerve damage
• serious allergic reaction
• infection at the site of injection: may require antibiotics and further treatment
• cardiac arrest (very rare)
• seizures (very rare)
• death (very rare).

In the event that participation in this research uncovers a medical condition which you were unaware, optimal care will be taken to disclose the condition to you and manage according to best practice guidelines. We will refer to your GP and refer you to a relevant specialist.

The effects of axillary block on the unborn child and on the newborn baby are not known. Because of this, it is important that research project participants are not pregnant or breast-feeding and do not become pregnant during the course of the research project. You must not participate in the research if you are pregnant, trying to become pregnant or breast-feeding. Women will have to take a pregnancy test prior to enrolment if there is a possibility that they are pregnant. Men should avoid unprotected sex and should not donate sperm for at least 24 hours after the procedure.

If you do become pregnant whilst participating in the research project, you should advise your study doctor immediately. Your study doctor will withdraw you from the research project and advise on further medical attention should this be necessary. You must not continue in the

research if you become pregnant. For men, you should advise your study doctor if you make someone pregnant within 24 hours after receiving medication for the procedure. Your study doctor will advise on medical attention for your partner should this be necessary.

If you become upset or distressed as a result of your participation in the research, the study doctor will be able to arrange for counselling or other appropriate support. Any counselling or support will be provided by qualified staff who are not members of the research project team. This counselling will be provided free of charge.

10 What will happen to my test samples?

Blood tests are already performed as part of the work-up for these procedures and these be reviewed prior to enrolment in the study as per standard practise. This is important to ensure your safety and appropriateness to be enrolled in the study.

Samples of your blood obtained for the purpose of this research project *will* be transferred to *NSW health pathology service*. Your blood or tissue will not be sold by Liverpool Hospital, however NSW may charge study doctors a fee to recover some of the costs of storing and administering the tissue samples.

Once your blood samples are transferred to *NSW health pathology*, Liverpool Hospital will not be able to control whether the *NSW health pathology* transfers or sells your samples at some future date, however *Liverpool hospital* will not knowingly transfer your samples to anyone who has expressed intent to sell the samples.

11 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.

Also, on receiving new information, your study doctor might consider it to be in your best interests to withdraw you from the research project. If this happens, he/she will explain the reasons and arrange for your regular health care to continue.

12 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.

It may also be necessary for you to take medication during or after the research project to address side effects or symptoms that you may have. You may need to pay for these medications and so it is important that you ask your doctor about this possibility.

13 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.

If you do withdraw your consent during the research project, the study doctor and relevant study staff will not collect additional personal information from 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 sponsor 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.

14 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 drug/treatment/device being shown not to be effective
- The drug/treatment/device being shown to work and not need further testing
- Decisions made in the commercial interests of the sponsor or by local regulatory/health authorities.

15 What happens when the research project ends?

At the end of the research project, the information and data will be processed and reviewed. If the data indicates that use of axillary block provides improved patient experience and/or procedural outcome in patients undergoing fistuloplasty in interventional radiology, then axillary block will be offered to patients undergoing interventional radiology procedures as part of standard care in the future.

Part 2 How is the research project being conducted?

16 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. Your information will remain coded into the data and can be re-identifiable, access to the data will be limited to the researchers listed in the study and the files will be stored electronically with password encryption at Liverpool Hospital. Your information will be stored for 15 years (minimum length for clinical trial research) and after this period, will be discarded. 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.

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. Specific names or birth dates will not be presented in any research presentation forms, data access will only be limited to the researchers listed and the information will be password encrypted in order to maintain confidentiality.

Information about your participation in this research project may be recorded in your health records.

In accordance with relevant 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.

17 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.

If there are complaints regarding your treatment by members of staff, you may contact the clinical trials coordinator in order to lodge a complaint. This will ensure that a formal system of review is conducted in order to prevent further instances from arising.

There are avenues that may be available to you for seeking compensation if you suffer an injury as a result of your participation in this research project:
• You may be able to seek compensation through the courts.

18 Who is organising and funding the research?

This research project is being conducted by the Liverpool Interventional Radiology Department, including Dr Ross Copping, and Dr Louise Wei.

There is no sponsorship or funding for this study.

Liverpool Hospital and the interventional radiology department will not benefit financially from this research project. Similarly, you will not benefit financially from your involvement in this research project.

In addition, if knowledge acquired through this research leads to discoveries that are of commercial value to the study doctors or their institutions, there will be no financial benefit to you or your family from these discoveries. No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

19 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 HREC of South West Sydney Local Health District (SWS LHD).

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.

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 8738 7056 or any of the following people:

Clinical contact person

Name	
Position	
Telephone	
Email	

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

Reviewing HREC approving this research and HREC Executive Officer details

This study has been approved by the South Western Sydney Local Health District Human Research Ethics Committee. Any person with concerns or complaints about the conduct of this study should contact the Research and Ethics Office, Locked Bag 7103, LIVERPOOL BC NSW 1871 on 02 8738 8304 / fax 02 8738 8310 / email SWSLHD-ethics@health.nsw.gov.au, website: http://www.swslhd.nsw.gov.au/ethics/default.html and quote 2021/ETH00524.

Thank you for taking the time to consider this study.
If you wish to take part in it, please sign the attached consent form.
This information sheet is for you to keep.