Northern Adelaide Local Health Network

Participant Information Sheet/Consent Form

Comparative Study - *Adult providing own consent*

Lyell McEwin Hospital

Title	Acquire versus ViziShot needles in Endobronchial Ultrasound Guided Lymph Node Aspiration
Short Title	ACQUI-SHOT Trial
Protocol Number	142.21
Coordinating Principal Investigator/ Principal Investigator	Dr Moayed Alawami
Associate Investigator(s)	Dr. Thanuja Singankutti Mudalige Dr. Shanka Karunarathne
Location	Lyell McEwin Hospital

Part 1 What does my participation involve?

1 Introduction

You have been referred by your Respiratory Physician to have a biopsy of your lymph nodes in your chest and we invite you to be involved in our research project. This research project is comparing two currently available needles to take the samples from your lymph nodes.

This Participant Information Sheet/Consent Form will provide you with all the information regarding the research project including the tests and treatments involved. This information should then help assist you to decide if you would like 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 to take part or not, 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 regardless of you participation.

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?

There are two needles that are approved by Therapeutics and Goods Administration for taking samples from mediastinal (chest) lymph nodes. Currently, we do not know if one needle is superior to the other and this study seeks to evaluate the use of these two needles. Both needles are available for routine use, but different institutions have different preferences with regard to these needles and we aim to study them and assess their accuracy in obtaining a diagnosis.

We anticipate that one needle is superior to the other. The results of this study may improve our current practice and potentially reduce the number of biopsies needed.

The results of this research will be used by the study investigator, Dr Moayed Alawami, to obtain a Master of Biostatistics degree.

This research has been initiated by the study doctor, Dr Moayed Alawami/Dr Shanka Karunarathne. This research is not funded and not sponsored commercially.

3 What does participation in this research involve?

We are comparing 2 biopsy needle types routinely used to samples from lymph nodes. Your routine care will not change, and you will receive a follow up phone call 7-10 days after your biopsy. The needle type will be chosen at random with 50:50 chance. Apart from the scheduled phone call, there are no other commitments or appointments related to this project.

Although the choice of needle is randomised, the onsite cytologist confirms if we have obtained a satisfactory sample or not. If one needle provides unsatisfactory sample, the senior doctor on duty can change the needle type in order to obtain satisfactory sample. We anticipate for this to occur very rarely.

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.

You will not be reimbursed for any reasonable travel, parking, meals and other expenses associated with the research project visit.

While it is desirable that your local doctor be advised of your decision to participate in this research project, it is likely that respiratory specialists, who perform this procedure routinely, are the only doctors who are interested in the outcome of this study.

4 What do I have to do?

As a participant we will be asking you to complete a 5 min phone call with Respiratory Nurse Consultant to ask you some questions around your symptoms a week later.

5 Other relevant information about the research project

We are aiming to recruit a total of 120 participants to get an accurate assessment of each needle. This study is only performed at Lyell McEwin Hospital. Each participant will be randomly assigned to one needle type. However, your doctor can change the needle type if he/she feels it is necessary (i.e. in case of no tissue obtained despite best efforts or any other concerns). This ensures that participants are not disadvantaged by the assigned needle and participants' interest are the most important consideration.

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. For those who do not participate in this project They will receive fair medical treatment and the same procedure, but the choice of needle is up to the doctor performing the procedure rather than random allocation by study investigators.

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 whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with Lyell McEwin 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. You can ask your doctor to make the decision on which needle to use according his/her judgement rather than randomly assigned needle type (note this would mean that you are not eligible to enrol in our study). Your study doctor will discuss these options with you before you decide 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?

There will be no clear benefit to you from your participation in this research. However, your participation may help future patients to have fewer biopsies.

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

Your treating team have discussed and decided with you that you need bronchoscopy and biopsy. The risks of biopsies are the same with both needles used. The following table shows the main side effect of having a mediastinal lymph node biopsy:

Side Effect	How often is it likely to occur?	How severe might it be?	How long might it last?
Post biopsy bleed (coughing blood)	less than 1 in 1,000	usually mild like bruising when taking blood samples from your arm.	Less than a week.
Introducing an infection (infection in lymph nodes or lung infection)	less than 1 in 1,000	usually mild and treated with oral antibiotics.	Treatment for one week.
Pneumothorax (introducing air into area between lung and chest wall causing lung to collapse)	Less than 1 in 1,000	This is usually a serious complication and likely results in an admission to hospital. It may need an intervention such as chest drain insertion.	Less than a week.
Inadvertent injury to major structures.	Very rare as we are using ultrasound to visualise needle position.	Usually any bleed is managed cold saline and adrenaline (standard practice).	Less than a week.

The above risk is based on using a needle for biopsy and does not consider that having a bronchoscopic examination in itself has it is own risk such as sore throat, cough, low oxygen saturation. You will be informed of these risks as part of your routine consent for bronchoscopic procedures on the medical treatment consent form. The risks related to having a bronchoscopic examination are not related to this study. We are only evaluating the performance of a needle that is used to take samples rather than the full procedure.

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?

The research project is assessing needles used to obtain mediastinal lymph node tissue sample rather than obtaining tissue for research. Your tissue samples go to an accredited pathologist who reviews tissue sample and provides a written report to the referring doctor as a routine. In other words, the research project aims to improve the quality of tissue obtained. Research investigators are not storing samples or doing extra tests for the purpose of research.

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?

It is unlikely that you need to change any treatment that you are being given since we are assessing needles to obtain tissue which is not known to be affected by any known treatment. 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. As a routine with all biopsies performed in health care, a history of previous bleed and/or taking anticoagulation (blood thinners) will be assessed and you must withhold blood thinners prior to procedure. This practice would be still the same in this research. We only invite participants to this research only if they followed the advice regarding stopping their blood thinners prior to procedure. Your study doctor should advise you when to restart your blood thinners (usually next day). You should also tell your study doctor about any changes to these during your participation in the research project.

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. It is unlikely that your withdrawal has any implications on your health.

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
- One needle is shown not to be effective
- One needle is shown to work superior to the other needle and not need further testing

15 What happens when the research project ends?

At the end of this research project, investigators will compare diagnostic yield of each needle used and assess if one needle is superior or equivalent to the other needle. It is likely that results will be presented in national or international conferences related to respiratory medicine.

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. Only study investigators will have access to your personal information and will be removed during analysis of research outcomes. 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. It is unlikely that we present any identifiable information since we are not taking any identifiable information (ie not taking photographs).

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 *and for the future research described in Section 16* 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.

18 Who is organising and funding the research?

This research project is not funded.

You will not benefit financially from your involvement in this research project even if, for example, knowledge acquired from analysis of your samples prove to be of commercial value to the manufacturer of biopsy needle that prove to be superior.

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages). Study investigators declared that they do not have any conflict of interest in relationship to this project.

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 Southern Adelaide Health Network.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007, updated 2018)*. 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 (Dr Alawami, 24-hour medical contact) on 08 8182 9000 (mention Acqui-Shot Study) or any of the following people:

Clinical contact person

Name	Taylar Tallboy
Position	Lung Cancer Nurse Consultant
Telephone	0401 142 496 (Only Mon-Friday during business hours)
Email	taylar.tallboy@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

Position	*Manager, Research Governance and Ethics*
Telephone	8204 6453
Email	Health.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 approving this research and HREC Executive Officer details

Reviewing HREC name	SALHN HREC
Position	Executive Officer
Telephone	8204 6453
Email	Health.SALHNOfficeforresearch@sa.gov.au
Reference number	142.21

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

Name	Lorraine Cichon
Position	NALHN Research Governance Officer
Telephone	08 8182 9346
Email	healthnalhnrgo@sa.gov.au
Reference number	21-128

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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 study investigators 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 _____

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.

☐ I would like to be informed about the outcome of this study. Please email _____

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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.

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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 Lyell McEwin Hospital.

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.