

**Participant Information Sheet/Consent Form**

**Interventional Study** -*Adult providing own consent*

*St Vincent’s Private Hospital- East Melbourne Campus*

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| **Title** | A Randomised control trial of Local infiltration  anaesthetic (LIA) versus LIA + 48 hours infusion of local anaesthetic postoperatively in anterior approach total hip replacement. |
| **Short Title** | LIA vs LIA + 48 hour infusion in Anterior THR |
| **Project Number** |  |
| **Project Sponsor** | Nil |
| **Coordinating Principal Investigator/ Principal Investigator** | Mr Phong Tran |
| **Associate Investigator(s)** | Dr Maya Keeka |
| **Location** | St Vincent’s Private Hospital  East Melbourne Campus  159 Grey St  East Melbourne  VIC 3002 |

**Part 1 What does my participation involve?**

**1 Introduction**

You are invited to take part in this research project. This is because you have osteoarthritis of the hip that can be treated by a total hip replacement. The research project is testingwhether adding a wound catheter that delivers local anaesthetic for up to 48 hours after surgery will help reduce pain levels and reduce the amount of pain killers that are needed after surgery.

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?**

The aim of this study is to determine whether infusion of local anaesthetic into the wound for 48 hours after hip replacement surgery reduces the pain after surgery, the amount of pain killers used and the length of stay after surgery.

The local anaesthetic is delivered by a device called the On-Q pump. The pump is inserted during your surgery and will remain in the wound site for 48 hours. The nursing staff will then remove it whilst your on the ward. The On-Q pump has been previously found to be safe to use and reduces pain in other types of operations.

This research has been initiated by Mr Phong Tran and Dr Maya Keeka

**3 What does participation in this research involve?**

You have been selected to participate in this research as you have osteoarthritis of the hip that can benefit from having an anterior total hip replacement. All participants will receive the same surgery with the same level of standard of care. Each participant will be randomly selected into one of 2 groups. Group A will receive local infiltration anaesthetic to the surgical site during the operation, whilst Group B will receive local infiltration anaesthetic during the operation as well as an On-Q pump wound catheter that will provide continuous local anaesthetic to the wound site for 48 hours after the surgery. After 48 hours, the On-Q pump will then be removed by the nursing staff on the ward which is easily removed.

The post-operative standard of care is the same regardless of which group you have been allocated to. There will be an equal number of participants in each group, therefore you have a 1 in 2 chance of being allocated to either group.

This is 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). 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?**

There are no additional requirements of you if you choose to participate in this study. Your surgery will be provided with the same standard of care if you were not participating in this study. There are no changes to the operation procedure and no changes to your post-surgical care by the nursing staff or physiotherapy other than extracting the wound catheter after 48 hours (if you are allocated to the group that receives the additional 48 hours of local anaesthetic).

The exclusion criteria for this study includes allergy or intolerance to Ropivicaine (local anaesthetic), and patients who have been diagnosed with Chronic Regional Pain Syndrome (CRPS). If you have either of these then you must let your surgeon know as you cannot participate in this study for safety reasons.

There are no lifestyle, dietary, or medication restrictions if you participate in this study. There are no questionnaires or forms for you to fill out if you participate in this study.

**5 Other relevant information about the research project**

If you choose to participate in this study, you will one of 108 patients enrolled. You will be randomly allocated to either Group A (Local Anaesthetic during surgery only) or Group B (local anaesthetic during surgery + local anaesthetic infusion for 48hours post surgery). All operations will be performed at St Vincent’s Private Hospital in East Melbourne by your surgeon Mr Phong Tran. The date of your surgery will be determined at your outpatient appointment with your surgeon and there will be no delay in having your surgery because you have enrolled in this study.

**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 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 St Vincent’s Private 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. The other option is to receive routine surgical care by your surgeon Mr Phong Tran which may not include having a wound catheter that delivers local anaesthetic infusion for 48 hours after your surgery. Your study doctor will discuss these options with you before you decide whether 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 improved pain relief, decreased use of pain killers and reduced length of stay.

**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 are worried about them, talk with Mr Tran. Mr Tran 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 that you get.

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 surgeon Mr Phong Tran may need to stop your treatment. Mr Tran will discuss the best way of managing any side effects with you.

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| Side Effect | How often is it likely to occur? | How severe might it be? | How long might it last? |
| Pain at surgical site | All patients will have  pain postoperatively  at the wound site | Minimal to severe,  but this will be  managed with  appropriate pain  killers if required | The pain is likely to last  for a few weeks,  gradually improving  throughout this time |
| Infection | Unlikely, less than 1% risk | Minimal to severe  (likely to be minimal,  may require  antibiotics or  additional surgery) | After starting proper  treatment, symptoms  should last less than a  week |
| Haematoma (collection  of blood under skin at  site of operation) | Unlikely less than 1% risk | Minimal to severe | It may last up to a  couple of weeks if  managed without an  operation. In some  circumstances, a  second operation is  required to drain the  haematoma. |
| Anaesthetic risks associated with routine anaesthesia for surgery  including damage to  teeth, sore throat,  nerve injuries, death | Very unlikely  Chance of damage  to teeth – 1 in 100  Chance of sore  throat – 20-45%  depending on type  of anaesthetic  technique  Chance of nerve  injuries 1 in 500  Chance of death 1  in 100,000 | Minimal to severe | Sore throat improves  over a few days. Nerves  may recover over weeks  to years |

If through participation in this project, a previously unknown medical condition is uncovered you will be counselled on the significance of this and how and where to seek appropriate management. This will be at no additional cost to you.

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.

Having a drug injected or blood (or tissue sample) taken 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 risks associated with anaesthesia. The most common problems associated with anaesthesia are feeling unwell or vomiting, bruising at the site of injections, sore throat or hoarse voice. Most patients 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.

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, they will explain the reasons and arrange for your regular health care to continue.

**11 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.

**12 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.

**13 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

**14 What happens when the research project ends?**

If you wish to be advised of the results of this study, please inform the principal or associate

investigator. This data will be provided as grouped data and will not relate to individual

participants. This data will be available in electronic or paper form approximately one year

after your recruitment.

**Part 2 How is the research project being conducted?**

**15 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. Electronic information will be stored in a re-identifiable state, whereby you are given a unique participant number which may be used to re-identify you if details need to be checked. The files containing your personal information will be kept securely in a locked filling cabinet which only the project investigators Mr Phong Tran and Dr Maya Keeka will have access to. All your inpatient data will be kept within your inpatient notes and stored in Medical Records as per the standard protocol for St Vincent’s Private Hospital.

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.

Your health records and any information obtained during the research project are subject to inspection (for the purpose of verifying the procedures and the data) by the relevant authorities, the institution relevant to this Participant Information Sheet, St Vincent’s Hospital Melbourne, or as required by law. By signing the Consent Form, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.

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 will be presented as grouped statistics so that no specific data is used that could potentially identify you.

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

In accordance with relevant Australian and/or Victorian 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.

**16 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 you have any complaints about any aspect of the study or the way in which it is being conducted you may contact the Patient Representative at St Vincent’s Private Hospital on Telephone: (03) 9411 7439. You will need to tell the Patient Representative the name of the person who is noted above as the principal investigator (Mr Phong Tran).

If you have any questions about your rights as a research participant, then you may contact the Executive Officer Research at St Vincent’s Hospital (Melbourne) on Telephone (03) 9288 3930.

In the event of loss or injury, the parties involved in this research project have agreed to provide compensation by the Principal Investigator’s Insurance Company.

**17 Who is organising and funding the research?**

This research project is being conducted by Mr Phong Tran and Dr Maya Keeka

**18 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 St Vincent’s Hospital Melbourne.

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.

**19 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 9928 6163or any of the following people:

**Clinical contact person**

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| --- | --- |
| Name | Mr Phong Tran |
| Position | Consultant Orthopaedic Surgeon |
| Telephone | (03) 9928 6163 |
| Email | Phong.tran@wh.org.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:

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| Reviewing HREC name | St Vincent’s Hospital Melbourne Human Research Ethics Committee |
| HREC Executive Officer | Dr Tam Nguyen |
| Telephone | (03) 9231 3930 |
| Email | Tam.Nguyen@svha.org.au |

**Reviewing HREC approving this research** **and HREC Executive Officer details**

**Consent Form –**

*Adult providing own consent*

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| --- | --- |
| **Title** | A Randomised control trial of Local infiltration  anaesthetic (LIA) versus LIA + 48 hours infusion of local anaesthetic postoperatively in anterior approach total hip replacement. |
| **Short Title** | LIA vs LIA + 48 hour infusion in Anterior THR |
| **Protocol Number** |  |
| **Project Sponsor** | Nil |
| **Coordinating Principal Investigator/**  **Principal Investigator** | Mr Phong Tran |
| **Associate Investigator(s)** | Dr Maya Keeka |
| **Location** | St Vincent’s Private Hospital  East Melbourne Campus  159 Grey St  East Melbourne  VIC 3002 |

**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 St Vincent’s Private Hospital 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.

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|  | | | | | | |
|  | Name of Participant (please print) | |  |  |  |  |
|  | | | | | | |
|  | Signature |  | | Date |  |  |
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|  | Name of Witness\* to Participant’s Signature (please print) | |  | | |  |
|  | | | | | | |
|  | Signature |  | | Date |  |  |
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\* 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.

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**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.

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|  | 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.

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**Form for Withdrawal of Participation –**

*Adult providing own consent*

|  |  |
| --- | --- |
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| **Short Title** | LIA vs LIA + 48 hour infusion in Anterior THR |
| **Protocol Number** |  |
| **Project Sponsor** | Nil |
| **Coordinating Principal Investigator/**  **Principal Investigator** | Mr Phong Tran |
| **Associate Investigator(s)** | Dr Maya Keeka |
| **Location** | St Vincent’s Private Hospital  East Melbourne Campus  159 Grey St  East Melbourne  VIC 3002 |

**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 St Vincent’s Private Hospital.

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|  | | | | | | |
|  | Name of Participant (please print) | |  |  |  |  |
|  | | | | | | |
|  | Signature |  | | Date |  |  |
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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.

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**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.

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|  | Name of Study Doctor/  Senior Researcher† (please print) | |  | | |  |
|  | | | | | |  |
|  | Signature |  | | Date |  |  |
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† 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.

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