**PIANOFORTE - P**rosthetic joint **I**nfection in **A**ustralia and **N**ew Zealand: c**O**mparing di**F**ferent antibi**O**tic strategies in a **R**andomised **T**rial **E**valuation.

We invite you to participate in a clinical trial comparing treatment strategies for prosthetic joint infections (PJIs) of the hip or knee.

This study is being carried out on behalf of the **Australasian Society for Infectious Diseases Clinical Research Network**. The chief investigators of the study overall are A/Prof Joshua Davis (John Hunter Hospital, Newcastle) and A/Prof Laurens Manning (University of Western Australia).

The principal investigator at this site is A/Prof Joshua Davis 49 22 3444

***This study has been approved by the Hunter New England Human Research Ethics Committee***

If you decide to take part in this research study, it is important that you understand the purpose of the study and what it involves for you. Please read the following pages, which will give you information about the procedures involved, and also the potential benefits and risks of the study. If English is not your first language and you would like to use an interpreter, please let us know and we will provide one for you.

This study is being done at five hospitals in Australia and New Zealand.

**Why is the study being done?**

“Prosthetic joints” are artificial versions of joints such as hips or knees, and are made of metal, plastic and other materials (see figure 1). They are commonly used to replace a person’s own joint if it has been damaged by arthritis, fractures or other problems. Prosthetic joint infection (PJI) is an uncommon, but severe complication of joint replacement surgery that occurs in 1-3% of patients following joint replacement surgery.

Treatment of PJI is usually with a combination of surgery and antibiotic therapy. You are being invited to take part in this study because you and your treating team have decided to treat your infection by cleaning up the prosthesis with an operation (called debridement), but leaving the prosthetic joint in place, along with a course of intravenous (meaning into to vein) and oral (meaning swallowing pills) antibiotics. It is not known how long a course of intravenous antibiotics is needed. Some experts recommend 2 weeks, some 6 weeks, and others somewhere in between. Most experts agree that oral antibiotics should be given for around 2 to 3 months.

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Hence we are planning this study to compare a 2 week course with a 6 week course of intravenous antibiotics combined with 10 weeks of oral antibiotics in both groups.

*Figure 1 – A prosthetic knee joint*

 **What will the study involve for me?**

If you give consent to be in the study, we will “randomise” you (like flipping a coin) to either receive 2 weeks or 6 weeks of antibiotics into the vein, counted from the time of your first “debridement” operation (to clean up the infected prosthesis). Whichever group you are allocated to, you will also receive 10 weeks of oral (tablet or capsule) antibiotics (see table 1). Which antibiotics you receive will depend on the type of germ that’s causing your infection.

We will collect information about your infection and how it is treated, any side effects of your antibiotics and your progress over time. Apart from the duration of intravenous antibiotics, all of your treatment will be determined by your own doctors.

Information will be collected by a doctor or nurse from the study team about the following:

* Information about you such as age and gender
* details of other illnesses
* details of the current infected prosthesis
* symptoms and signs of infection
* treatment received
* any side effects of treatment
* blood test results

This information will be collected over the next 12 months. This data collection will coincide with planned orthopaedic, infectious diseases or other appointments at the hospital, and you will not be required to make any special trips to the hospital just for this study. With your permission we will also access your medical records and may contact your other doctors (such as GPs or orthopaedic surgeons) during this follow up period to check your progress.

Approximately 12 months after enrolment, we will try to contact you by telephone to see how you are going, how your hip or knee is functioning and whether you have needed any more treatment for it.

 **Table 1 – Duration of intravenous and oral antibiotic therapy in the two study groups**.



**Benefits**

It is unlikely that this study will be of direct benefit to you. However, we anticipate that the results of this study will lead to better understanding of how to treat PJIs that will, in turn, benefit other patients with this infection in the future. You will not receive any payment for participating in this study. The costs of all your treatment will be the same whether you participate in the study or not.

**Discomforts and risks**.

All antibiotics may have side effects (for example diarrhoea or rash). However, you will be receiving the same antibiotics whether you agree to participate in this study or not. If you are allocated into the “short” treatment group, you will be receiving less intravenous antibiotics than in the standard group. There is a potential risk that this will not be enough antibiotics to cure your infection. This is very unlikely, because you will be receiving 10 weeks of oral antibiotics, and previous studies suggest that 2 weeks is probably long enough (although we don’t know this for sure, and this is the reason for doing this trial).

On the other hand, if you are in the 6 week group, there are potential risks of side effects from the longer course of intravenous antibiotics, and from having a PICC line (a long thin tube that goes into a vein in your arm and can stay in place for weeks if needed) in place for longer. A PICC line will be needed in almost all participants in both groups (as it is routine to use one where >10 days of intravenous medication is needed). Around 1-2% of people with a PICC line present for 4 weeks develop a blood clot in their arm veins which can cause pain and swelling (also known as a “DVT”), and about 1 in 1000 develop a blood stream infection because of the PICC line. The longer a PICC line is in, the more these risks increase.

Whichever treatment group you are allocated to, your treating doctor is able to give you a longer course of intravenous antibiotics if he/she thinks it is necessary.

**Confidentiality**

In this study, we will collect identifiable information about you. This will include your date of birth, date of hospital admission and hospital record number. All information generated will be treated with respect, stored securely and held in strict confidence. No information concerning the study or the data will be released to any unauthorised third party. No identifiable or traceable information about you will be available to the public, or in any reports arising from this research. Blood or human tissue samples will not be stored.

**Voluntary Participation and Withdrawal from Study**

Your participation in this study is entirely voluntary and you may withdraw from this study at any time, for whatever reason. Such withdrawal will not in any way influence your relationship with the researchers or the health service providing your care in the future. If you do choose to withdraw from the study, you have the option of requesting that all your personal information is destroyed and we will comply with your wishes. Any decision you make will not affect your treatment or relationship with the Hunter New England Local Health District.

**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 Hunter New England 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.

**Further information and who to contact**

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,

[Kellie Schneider] on [49 22 3444] or [kellie.schneider@hnehealth.nsw.gov.au], or the principal study doctor, Dr Josh Davis on email Joshua.Davis@hnehealth.nsw.gov.au.

**Complaints about this research**

If you have any queries about the ethical approval of this project, or with to make a complaint to an independent person, please contact the approving ethics and local research governance contact: Dr Nicole Gerrand, Manager, Research Ethics and Governance Unit, Hunter New England Human Research Ethics Committee, Hunter New England Local Health District, Locked Bag 1, New Lambton NSW 2305, telephone (02) 49214950, email hnehrec@hnehealth.nsw.gov.au, and quote reference number [insert SSA reference number]

**Thank you for taking the time to consider this study. If you wish to take part in it, please sign the attached consent form.**