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Central Northern Adelaide Health Service

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ProFNUL- Proximal Femoral Nail Unlocked vs Locked Trial – Participant Information Sheet

We are inviting you to take part in a clinical research study which is a comparison involving 2 different types of devices used to treat broken hips.

Before you decide whether to participate, it is important for you to understand why this study is being undertaken and what it will involve.

Please take time to read the following information carefully and discuss it with your family or other advisors, if you wish.

Please ask if you would like additional information or there is anything that is not clear.

Take your time to consider whether or not you wish to take part.

What is this trial about?

Broken hips such as yours are very common, and almost all are treated with an operation. At this hospital, around half of the operations for this injury involve using a device called a “Nail”, which is a rod inserted down the middle of the thigh bone to help hold the break whilst it heals. At the top of this rod there is a long screw that is inserted up towards the hip joint, that adds more stability to the broken bone.

This trial has two aims. The first is to compare two different makes of Nail – they are both well tried and tested designs, but from different companies, each considered ‘standard practise’ by different surgeons and at different hospitals. In spite of this, no direct comparison exists to help us decide which to use. The second aim of the study is related to the screw at the top of the nail. This screw can be inserted in two different ways – one is called “unlocked” which means it can slide up and down, whilst the other is called “locked” which means it is fixed in place. Some surgeons always use a “locked” mode, some always use an “unlocked” mode, and some decide for each individual case. There is no good evidence available to help guide this decision, and so we are aiming to get information from this trial to help us decide whether this screw should be fixed or allowed to slide, potentially

improving the future treatment of broken hips. In order to answer these questions we need to compare large numbers of patients, and our aim is to include a total of 900 patients in this study, over a 3 to 4 year period.

Why have I been asked to participate?

You have broken your hip, and your surgeon has already decided that you need an operation using a type of Nail. We would therefore like to consider enrolling you into this trial.

What will happen if I agree to take part?

If you agree to take part, you will be randomly assigned to receive one of the 2 different types of Nail, and also whether the screw at the top will be locked or unlocked. Randomisation is like flipping a coin – neither you nor your treating surgeon will be able to choose which device you receive, or whether the nail is locked or unlocked at the top.

Your operation will still take place in the normal way at the same time, by the same surgeon, the only difference will be which device is used in surgery, and how it is used with regard to the mode of the screw at the top.

After surgery we would normally review you up to one year after surgery, typically at six weeks, six months and 12 months. For this study, we are planning to review you in the clinic at six weeks and six months - we will ask you to fill out some forms to tell us about your hip pain and general function at each visit. This should take you around 20 minutes at each visit. There are no extra clinic visits required, and no extra X-rays to be taken.
You will not know which Nail has been used, although we will tell you if you want to know, after the 6 month final assessment.

In the event of general complications involving the treatment device (i.e. device failure), we may ask for consent for a bone biopsy to be taken. In this event, we will seek your consent before doing anything.

Are there any risks to me if I agree to take part?

There is no additional risk involved in the surgery or recovery process. It is possible that when the trial is complete you will have been randomly assigned to a group of patients that are shown to do less well, however it is not possible to tell that until the trial is completed. There are no out of pocket expenses associated with this trial.

What if something goes wrong?

All surgery has some risk, which will be discussed with you separately by your treating doctor or team. The additional risk of being involved in this study is felt to be very small. However, the study is indemnified by SA Health, and in addition you retain the right to seek compensation through the legal system.

What will happen if I refuse to take part?

If you don't want to take part in the trial then there is no problem with this. Your surgery will go ahead exactly as planned, and you will whichever Nail your surgeon chooses. There will be no change in your follow-up plans either.

What if I want to pull out of the study after surgery?

If you no longer wish to participate in the trial, then you are free to withdraw at any point. There will be no effect on your care as a result of this.

What are the potential benefits of this study?

You will not receive any direct benefits or payment for being in this study. however the information gained from this trial will help simplify decision making for future patients, and hopefully lead to also improved outcomes for the patients.

Who is organising and funding the research?

This study is being organised and run by Associate Professor Mark Rickman, as part of the department of Orthopaedics & Trauma at the Royal Adelaide Hospital.
The study will be performed according to the NHMRC National Statement on Ethical Conduct in Human Research, a document prepared to protect the rights of participants in medical research studies
Funding has been provided via a Research Grant, that was awarded by Smith & Nephew. Smith & Nephew manufacture one of the devices used in this study, however they do not have any control of any aspect of the study (it is independent of them as the funding was awarded as a grant). In addition, the data and outcomes from the study are owned by the University of Adelaide / Royal Adelaide Hospital and not by Smith & Nephew. The company however may benefit in that this will result in publication of a large volume of outcome data on patients managed with their device.

All research in medicine is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been carefully approved by the Central Adelaide Local Health Network Human Research Ethics Committee – HREC reference number: HREC/17/RAH/433

Confidentiality and Data Security

Access to your medical records for information related to your operation and any post operative events will be required by the research team.

All the information collected during the study will be kept confidential. Data will be held on a secure database in the Royal Adelaide Hospital, protected from unauthorised access.

On the database, you will be identified by a unique study number, date of birth, date of operation and surgeon who performed your operation. Only the surgeon, and members of the research team will be able to identify participant's names. All parties are bound by strict confidentiality guidelines under the Australian Data Protection Laws.

At the end of this study, the data will be stored in the same secure manner for 10 years, before being deleted.

If you agree to participate you will be asked to grant consent for our research team to access your medical notes for data entry and to auditors for the purpose of verifying accuracy of data entered.

In addition to the processes described above, data may otherwise be discoverable through processes of law or for assessing compliance with research procedures.

You have a right to access the information collected and stored by researchers about you. You also have a right to request that any information with which you disagree be corrected.

You have a right to ask that any stored specimens be destroyed but should be aware that data which has already

A description of this clinical trial will be available on www.anzctr.org.au, as required by the Ethics Committee. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

What will happen to the results?

Whatever the trial shows, we plan to publish the outcome data as a paper in the medical literature, as well as present it at local and national meetings to disseminate the findings. No patients would be identified in any of these, and only total numbers of patients and outcomes will be shown.

Who do I ask if I have more questions?

If you have urgent questions, you can ask either the person who gave you this form, or your treating doctors. In addition, for less urgent questions you can ask the study co-ordinator A/Professor Mark Rickman, who can be contacted via his secretary on 08 707 42003.

If you wish to speak to someone not involved in the study about your rights as a participant, you may contact the Executive Officer of the Research Ethics Committee on 08 7117 2229 or CALHNResearchEthics@sa.gov.au

Study No: | | | |

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PATIENT CONSENT FORM

1. I confirm that I agree to take part in this study as described to me and that I was given the opportunity to ask all of the questions I had concerning my treatment and participation and that they were all answered to my satisfaction.

2. I also confirm that I have read and understood the patient information sheet and I have had the opportunity to discuss the patient information provided for me with members of my family and/or friends.

3. I understand that I will not benefit from taking part in this study.

4. I understand that if I withdraw or become unable to complete the study on medical grounds that data gathered prior to that time point may still be used for this study.

Patient Name ……

Signature …… Date ……

Consent Taken By …… Role……

Signature …… Date ……

Surgeon Name……

Surgeon Signature…….. Date……

Consent form – V 1.3 13/09/2018

Study No: | | | |

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Patient Consent Form for Gait Analysis & Activity Monitors

1. I confirm that I agree to take part in this part of the study as described to me and that I was given the opportunity to ask all of the questions I had concerning my treatment and participation and that they were all answered to my satisfaction.

2. I also confirm that I have read and understood the separate patient information sheet and I have had the opportunity to discuss the patient information provided for me with members of my family and/or friends.

3. I understand that I will not benefit from taking part in this study.

4. I understand that if I withdraw or become unable to complete the study on medical grounds that data gathered prior to that time point may still be used for this study.

Patient Name ……

Signature …… Date ……

Consent Taken By …… Role……

Signature …… Date ……

Surgeon Name……

Surgeon Signature…….. Date……

Consent form – V 1.3 13/09/2018

Study No: | | | |

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3rd Party Consent Form

1. I confirm that I agree for ……..to take part in this study as described to me and that I was given the opportunity to ask all of the questions I had concerning their treatment and participation, and that they were all answered to my satisfaction.

2. I also confirm that I have read and understood the patient information sheet and I have had the opportunity to discuss the patient information provided for me with members of my family and/or friends.

3. I understand that there is no benefit to us from taking part in this study.

4. I understand that if the patient becomes unable to complete the study on medical grounds that data gathered prior to that time point may still be used for this study.

Name …… Relationship to Patient……..…….

Signature …… Date ……

Consent Taken By …… Role……

Signature …… Date ……

Surgeon Name……

Surgeon Signature…….. Date……

Sivakumar A, *et al. BMJ Open* 2020; 10:e032640. doi: 10.1136/bmjopen-2019-032640