|  |
| --- |
| **Nhs The Newcastle upon Tyne Hospitals** |
| NHS Foundation Trust |
|  |
| **Participant Information Sheet** |

****

**Pilot study comparing Synovectomy vs. no Synovectomy in Total Knee Replacement**

We would like to invite you to take part in a research study.

This study aims to establish if removal of your knee lining at the time of your total knee replacement improves patient outcome. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully and discuss it with family and friends and/or GP before deciding to take part.

A Research Nurse will telephone you prior to your admission to discuss the study further.

***What is the purpose of the study?***

The study will compare two different surgical practices in Total Knee Replacement. We hope to learn if one type of practice is better at improving patient satisfaction, compared to another. Our aim is to investigate ways to improve results for your knee replacement.

***Why have I been invited?***

**You have been given this information booklet as your doctor has deemed that you are suitable to participate in this study as you have been listed for a knee replacement under the care of Professor Deehan or Mr Brewster.**

***Do I have to take part?***

It is up to you to decide to take part in the study. We will describe the study and go through this information sheet. If you decide to take part we will ask you to sign a consent form on the morning of your admission. You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive.

***What happens if I take part?***

If you agree to take part you will receive the same standard of care as you would normally receive when having a knee replacement at this hospital. On admission, a Research Nurse will speak to you and answer any questions you may have about the study. If you decide to participate you will be asked to sign a consent form and complete three brief questionnaires.

At time of your knee replacement the surgeon will perform the routine skin incision and the joint will be inspected. If there is thickening of the lining of the joint (synovium) then you will be randomly assigned to one of the two groups in the study.

**Group 1**

Will receive a normal total knee replacement. This is the operation described to you prior to consent for the knee replacement.

**Group 2**

Will receive a normal total knee replacement. IN ADDITION THE LINING OF THE JOINT ABOVE AND TO THE SIDES OF THE NEW COMPONENT WHICH IS ENLARGED WILL BE REMOVED. Removal of this tissue may influence the recovery of the knee after surgery. A sample of this tissue will be sent to Newcastle University to look at the levels of inflammation.

**Both groups** will receive the same postoperative care and follow up.

You will be seen at your routine follow up appointments at the outpatient department at 6-8 weeks and 12 months after surgery. Routine X rays and assessments will be carried out.

The research nurse will also carry out an assessment of your knee joint and ask you to complete the questionnaires again. These additional assessments should take approximately 20 minutes to complete. In addition you will be sent questionnaires to complete and return after six months.

**If the surgeon does not find evidence of synovial thickening in your knee joint there will be no further involvement in the study and your baseline questionnaires will be destroyed.**

**How long will I need to be involved in the research?**

The study will follow your progress for 12 months following your surgery. However, this will not affect your normal routine follow up beyond this time

**Is this procedure normally carried out?**

Yes, this procedure is often but not always performed and is left to the discretion of the individual surgeon. There is no clear agreement as to the correct option. Hence we wish to study the effect of such and identify which patients will gain the greatest benefit from this procedure.

**What are the potential disadvantages of taking part?**

The risk is deemed very low and is essentially the risks normally associated with this type of operation and these risks will be explained to you at the time of the operation, there is no additional risk associated with either group.

The potential benefits are less pain in the longer term following your total knee replacement. There may also be other benefits, such as improved range of motion.

**Will my taking part in the study be kept confidential?**

Yes, we will follow ethical and legal practice and all information about you will be handled in confidence.

**Will my GP be informed?**

Yes. If you agree, your GP will be informed as to your participation in the study and we will keep them informed of your progress. It is usual practice for the surgeon to write to your GP after surgery and your out-patient appointments.

**What if relevant new information becomes available?**

Sometimes we get new information about the treatment being studied. If this happens, your research doctor will tell you and discuss whether you should continue in the study.

**What if there is a problem?**

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the Patient Liaison and Advice Service (PALS) on 0800 032 0202 (Freephone).

**What will happen with the results of the study?**

The data generated from this study may be used for presentation or publication but you will not be identified as an individual at any time.

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given favorable opinion by a Research Ethics Committee (NRES Committee North East-Sunderland).

Thank you for taking the time to read this Patient Information Sheet. If you have any queries please contact Professor David J Deehan on 0191 213 7264, or the Research Nurse, Judith Coulson on 0191 223 1514.