NATIONAL ORTHOPAEDIC HOSPITAL CAPPAGH

Study Participant Information Leaflet

PROJECT NAME: The Efficacy of Peri-Articular Injection for Pain Relief Post Total Hip Arthroplasty. A Single-Centre, Double-Blinded Randomised Control Trial

Principal Investigator(s) and Co-Investigator(s)	**Mr James Cashman** **Dr Ross Condell (ross.condell@nohc.ie)**
Study Organiser/ Sponsor (if applicable)	**N/A**
Data Controllers	**National Orthopaedic Hospital Cappagh**
Data Protection Officer	**Data Protection Officer: Claire Falvey** **Contact details: dpo@nohc.ie and (01) 814 2447.**

You are invited to take park in a research study that is being performed by Mr James Cashman and Dr Ross Condell at the National Orthopaedic Hospital Cappagh.

Before you decide whether or not you wish to take part, please read this information sheet carefully. Ask your doctor in the National Orthopaedic Hospital Cappagh any questions. Don't feel rushed or under pressure to make a quick decision. You should understand the risks and benefits of taking part in this study so that you can make a decision that is right for you. You may wish to discuss it with your family, friends or GP.

This leaflet has five main parts:

Part 1 – The Research Project
Part 2 – Data Protection
Part 3 – Costs, Funding and Approval
Part 4 – Future Research
Part 5 – Further Information

NATIONAL ORTHOPAEDIC HOSPITAL CAPPAGH

Part 1 – The Research Project

Why is this study being done?

We are doing this study to analyse the effects of an injection given into soft tissues during a total hip replacement operation to help with pain relief. This injection consists of a mixture of local anaesthetic, adrenaline and saline. The effects of this injection are not fully understood, some surgeons use it regularly and some do not. Our hypothesis is that this injection given during the operation leads to improved pain control after the operation.

Why have I been invited to take part?

You have been invited to take part in this study as you have osteoarthritis and have been listed for a total hip replacement. If you are willing to take to part, we will be assessing your pain after the operation with a series of questions, as well as assessing your painkiller requirements. We are intending to involve around 120 participants who have osteoarthritis and require a total hip replacement. Half of these participants will receive the injection and half will not. The participants who do not receive the injection will be our control group for the study – this allows a comparison group to see what are the effects of the injection.

Do I have to take part? Can I withdraw?

You don't have to take part in this study. It is entirely voluntary. If you decide not to take part it won't affect your current or future medical care. You can change your mind about taking part in the study and opt out at any time. If you decide to opt out, it won't affect your current or future medical care. You don't have to give a reason for not taking part or for opting out. If you wish to opt out, please contact Dr Ross Condell (ross.condell@nohc.ie) who will be able to organise this for you.

NATIONAL ORTHOPAEDIC HOSPITAL CAPPAGH

What happens if I change my mind?

You can change your mind at any time by contacting your study Dr Ross Condell (ross.condell@nohc.ie). If you choose not to continue to take part, this will not affect your medical care in any way. If you wish, you can ask for your data stored to be destroyed. If you request this, we will destroy all data that is still in our possession. We will no longer use your data for research from this point onwards. However, it will not be possible to destroy data already used in research studies prior to this time.

How will the study be carried out?

Potential participants will be asked on the morning of their operation whether or not they would be willing to consent to participate in this research study. Willing participants will then be randomised to either receive the injection during the operation or not receive the injection. The patient will not be aware if they received the injection or not – this prevents bias towards answers provided later in the study. All other aspects of the operation will continue as normal regardless of the use of the injection or not. Participants will follow the standard post-operative rehabilitation plan on the ward with the nurses, physiotherapists and occupational therapists. They will then fill out three Visual Analogue Scale (VAS) forms with Dr Ross Condell. These forms are a method of assessing someone's pain at a certain point in time. The VAS forms will be filled out at the following times; 24 hours post-operation and after first mobilisation with physiotherapy. In order to formulate an analysis that is significant, there is a minimum of 128 participants required for the study and we foresee this taking approximately 4 months to reach.

What will happen to me if I decide to take part?

If you decide to take part in this study you will be randomly assigned to one of two groups. Randomisation of participants allows eliminates the selection bias, balances the groups with respect to known and unknown confounding variables. Group A will receive the injection and group B will not. Group B is the control group which allows a comparison to see what effect the injection has on pain relief after your operation.

The injection is called a 'periarticular injection' – this is an injection that is given in and around the hip joint soft tissues. This injection is given by your surgeon at certain stages of the operation. If you do receive the injection, you will not feel it as it is given during the operation when your lower body is numb. Your operation will not differ from normal other than the receiving or not receiving of the periarticular injection. Following your operation, the standard post-operation protocol will remain the same.

You will be asked to fill out a pain score form called a 'Visual Analogue Scale' at three different tie points; 24 hours after your operation, after mobilising with the physiotherapist, and 48 hours after your operation. Additionally, your painkillers requirements will also be assessed during your hospital

stay. Following your discharge from hospital, you will not be contacted again regarding the study.

What will happen to my Data?

Your data will be limited to; gender, age, Visual Analogue Scale scores and post-operation painkiller requirements. This data will be collected and analysed with data from other participants. No other identifiable data will be collected. The data will be stored on a secure shared drive and will not leave hospital grounds.

Once enough participants have taken part in the study, this data will be analysed to determine the overall effects of the periarticular injection. Any conclusions that are made from this study will be presented at conferences nationally and internationally, as well published in a medical journal for surgeons worldwide to see. The collected data will then be deleted.

Are there any benefits to taking part in this research?

Taking part in this study will not directly benefit you. However, research performed with your coded information may help us to better understand intra-operative injections for pain relief and may result in new tests, drugs or treatment approaches. This is a long-term research project, so the benefits of the research may not be seen for several years. By participating, you are helping to advance science and medicine for future generations.

Are there any risks to me or others if I take part?

Some pain after an operation is any expected. There are numerous techniques to relieve pain after a total hip replacement. These include options such as simple oral painkillers, mobilisation aids and limb elevation. The use of this injection is a potential additional form of pain relief. There is a risk that pain may be more intense for those not receiving the periarticular injection, however this is not for certain and is the basis of why this study is being performed.

There is a risk that a connection to your identity could be made. Great care will be taken to ensure the confidentiality of all data and the risk to participants of a breach of confidentiality is considered very low.

Will I be told the outcome of the study? Will I be told the results of any tests or investigations performed as part of this study that relate to me?

The results of the study will be reported in surgical journals and disclosed at surgical conferences. No information which reveals your identity will be disclosed.

NATIONAL ORTHOPAEDIC HOSPITAL CAPPAGH

Part 2 – Data Protection

What information about me (personal data) will be used as part of this study? Will my medical records be accessed?

Personal data will be limited to name, age and gender. No other personal identifying data will be recorded. Additionally, the painkillers that are required after your operation will be recorded – this will involve access to your medication Kardex that lists all of the medication you are given during your hospital stay, as well as any medications you are already taking regularly.

What will happen to my personal data?

Your data will be stored on a secure shared drive in the National Orthopaedic Hospital Cappagh throughout the study. It will be analysed and all results will be anonymised by Dr Ross Condell. No other individual will have access to this data. All data will be stored until processing and analysis is completed. Data will then be erased from all software computer systems (data storage time will be for no longer than 6 months – this allows sufficient time for analysis).

Who will access and use my personal data as part of this study?

Dr Ross Condell will have access to participant's personal data and medication Kardex. This data will not leave the hospital site.

Will my personal data be kept confidential? How will my data be kept safe?

Your privacy is important to us. We take many steps to make sure that we protect your confidentiality and keep your data safe. Here are some examples of how we do this: Data is always recorded on a secure shared drive. Once data is collected, it will be pseudo-anonymised to protect participant's identification. Data will be kept for the minimum amount of time required to process and analyse. Dr Ross Condell is trained in data protection law and bounded by professional code to maintain confidentiality.

What is the lawful basis to use my personal data?

By law,[1] we can use your personal information for scientific research[2] (in the public interest[3]). We will also ask for your explicit consent to use your data as a requirement of the Irish Health Research Regulations.

What are my rights?

You are entitled to:

- The right to access to your data and receive a copy of it
- The right to restrict or object to processing of your data
- The right to object to any further processing of the information we hold about you (except where it is de-identified)
- The right to have inaccurate information about you corrected or deleted
- The right to receive your data in a portable format and to have it transferred to another data controller
- The right to request deletion of your data

By law you can exercise the following rights in relation to your personal data, unless the request would make it impossible or very difficult to conduct the research. You can exercise these rights by contacting Dr Ross Condell or the NOHC Data Protection Officer.

[1] The European General Data Protection Regulation (GDPR)
[2] *Article 9(2) (j))*
[3] *(Article 6(1)(e)*

NATIONAL ORTHOPAEDIC HOSPITAL CAPPAGH

Part 3 – Costs, Funding and Approval

Has this study been approved by a research ethics committee?

Yes, this study has been approved by the National Orthopaedic Hospital Research Ethics Committee. Approval was granted on [INSERT DATE].

Who is organising and funding this study? Will the results be used for commercial purposes?

There is no funding for this study as it involves a therapy that is already used broadly within the hospital. Results will be presented nationally and internationally at meetings / conferences. Results will be published in a medical journal for the medical community to see. There is no funding or payments provided to the research study organisers.

Is there any payment for taking part? Will it cost me anything if I agree to take part?

No, we are not paying patients to take part in the study.

Part 4 – Future Research

Will my personal data be used in future studies?

No future research studies will be performed with your data. Consent for personal data will only be obtained for this current study. Your consent is voluntary and can be withdrawn at any time during the study. This research study will proceed only when research ethical approval has been obtained.

NATIONAL ORTHOPAEDIC HOSPITAL CAPPAGH

Part 5 – Further Information

Who should I contact for information or complaints?

If you have any concerns or questions, you can contact:

- Principal Investigator: Mr James Cashman, Orthopaedic Consulant, National Orthopaedic Hospital Cappagh
- Co-Investigator: Dr Ross Condell, Orthopaedic Specialist Registrar, National Orthopaedic Hospital Cappagh, ross.condell@nohc.ie
- Data Protection Officer: Claire Falvey, dpo@nohc.ie

Under GDPR, if you are not satisfied with how your data is being processed, you have the right to lodge a complaint with the Office of the Data Protection Commission, 21 Fitzwilliam Square South, Dublin 2, Ireland. Website: www.dataprotection.ie.

Will I be contacted again?

No, you will not be contacted again regarding this study.

If you would like to take part in this study, you will be asked to sign the Consent Form on the next page. You will be given a copy of this information leaflet and the signed Consent Form to keep.