[Insert Hospital Logo]

Patient Information Sheet for the Knee Replacement Bandaging Study (KReBS)

Dear Patient,

Study Title: ***A Randomised Controlled Trial of the effect of a Two-layer Compression Bandage System on Knee Function following total knee arthroplasty***

We would like to invite you to take part in our research study. Before you make a decision, we would like to explain why we are doing the study and what it would involve for you. Participation is voluntary and if you decide not to take part, the standard of medical care that you receive will not be affected. Please take the time to read the information sheet carefully and discuss with others if you wish. If you would like more information or something clarifying, or have any questions at all, please contact us via the details at the end of this document.
Thank you for taking the time to read this information.

What is the Purpose of this Study?

Total knee replacement has revolutionised the management of osteoarthritis. Despite this, knee swelling and stiffness are common post-operative complications. These complications can slow down the rehabilitation process and impact on your experience in hospital.

Currently, patients undergoing total knee replacement are enrolled in an enhanced recovery programme, which aims to ensure that patients receive the most optimal care before, during and after surgery. This involves many

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members of the healthcare team and ensures you have effective pain relief and are mobilised as early as possible, to ensure a quick but safe recovery.

Despite the success of the enhanced recovery programme, we are still looking at ways to improve our service further. Currently, patients wear normal bandages on their knee after surgery. However, recent studies from Europe indicate that a compression bandage worn around the knee for two days after surgery may improve pain and complications. Additionally, using research from compression bandage use in patients with other forms of leg swelling, we predict this may also reduce swelling and stiffness after surgery.

However, these findings have not yet been proven in a large, well-designed scientific study and so we do not know which of the treatments is better. The aim of this study is therefore to investigate whether compression bandages worn after knee replacement surgery improves pain and early function compared to normal bandages.

Why Have I Been Invited To Take Part?

You have been invited to take part as you are currently awaiting knee replacement surgery and also fulfil our criteria for the study.

What Would Taking Part Involve?

We hope to enrol approximately 2600 patients for the study from a number of hospitals across the UK. If you decide to be involved with the study, it means that you agree to receive either the compression bandage or the standard bandage after surgery. Which type of bandage you will receive is decided at random (or by chance) to try and eliminate any biases in the study.

You will receive one or the other to investigate whether the compression bandage makes a difference to what we are doing already. Your involvement in the study will not require any additional procedures or hospital visits other than those that you would have if you were not in the study.

You will also be asked to fill in two knee function and symptoms questionnaires before your surgery and again at your six month follow-up. These questionnaires are normal routine practice. You will also be asked to complete the same questionnaires at 12 months following your operation. This will be posted to you, together with a pre-paid envelope for you to return the questionnaire to us.

We will also ask the hospital to send us some of the routinely collected data about you (gender, date of birth and body mass index), your operation and hospital stay, and outcomes.

If you agree, we will also send you text messages via your mobile regarding your participation in the trial. Shortly after your operation you will receive an introductory text to explain that we will be sending text messages to collect data, and that these texts may come from a number of different numbers but will always begin with the trial name so that you can recognise it. Then at approximately 10 days, at 4 weeks and again at 12 months after your surgery, we will ask you reply to an SMS to provide us with a pain score. Opting out of this will not affect your participation in the overall trial.

In total, you will be enrolled in the study for twelve months following your operation.

Patient involvement in study

Listed for surgery in clinic	Given information sheet about study
Day of surgery	Research team check eligibility for the trial Research team consent for the trial and answer questions Fill out initial questionnaires
Surgery	Standard bandage or compression bandage applied
Post-operation	Routine care following surgery. Bandages removed prior to discharge
10 days post-operation	Text message asking about pain
4 weeks post- operation	A further text message asking about pain
6 months post- operation	Fill out and post back questionnaires (This happens routinely even for those not in the trial)
12 months post- operation	Fill out and post back final questionnaires. Text message asking about pain

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What are the Possible Benefits of Taking Part?

Because we do not know which of the treatments is better you might not benefit from taking part. If enough people take part in this study, the information we get should help to ensure that patients having knee replacement operations will receive the best treatment in the future.

Are There Any Disadvantages of Taking Part?

We do not foresee any disadvantages taking part in the study. There is a small chance of discomfort whilst wearing the compression bandage, which we will monitor during the study.

The compression bandage treatment is not routine practice in patients following total knee replacement. Currently it will not be continued when the study ends. However, should the study find that this is beneficial and economically viable this may be continued in the future.

Do I Have To Take Part?

No. It is for you to decide and is completely voluntary. If you decide not to take part, this will not influence your medical care or legal rights.

What will happen if I don't want to carry on with the study?

Even if you initially decide to take part and sign the consent form, you are free to withdraw at any time, without giving a reason. Withdrawing will not affect your future care or rights in any way.

It is for you to tell us that you no longer wish to take part. However, if you do decide to do this then we will know not to contact you in future. If this

happens, you should tell us whether you would prefer that we didn't contact the hospital for any further data and whether you would like your contact details to be deleted from the records. All the other data collected for you up to the time of your withdrawal from the study will be kept unless you request otherwise.

What Will You Do With My Records?

With your permission, we will inform your family doctor that you are taking part in the trial. We will also contact your GP if we have any concerns about your health during your participation.

Your medical notes will also be accessed by our researchers authorised to do so. The hospital trust and regulatory bodies overseeing this study may also need to access your medical notes. All authorised staff accessing your information will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

All the information that is used in the study will be anonymous. We will remove all names and other identifying information before the data are analysed and the results presented to the medical community at conferences and in scientific journals. This ensures that you cannot be traced back from any data that we use or publish.

At the beginning of the study we will record your name, address, telephone number and date of birth and keep a copy of your signed consent form. Your data will be held in a secure place at Northumbria Healthcare NHS Foundation Trust or at the University of York in accordance with the Data Protection Act 1998. All data will be held for a minimum of 5 years to comply with NHS policy and research guidance and will only be accessible to

authorised individuals. Paper data will be disposed of securely and electronic data will be anonymous of identifiable information. This anonymised data may be made available to other researchers and third parties following the trial.

Who Is Organising the Funding and Research?

The study intervention is being funded by 3M Healthcare. The sponsor is Northumbria Healthcare NHS Foundation Trust.

None of the surgeons involved will receive any direct payment for their involvement in the study. Finance has been made available from 3M for Northumbria Healthcare to run the study and as part of this, hospitals will receive a small payment to cover the costs of recruiting participants in to the study and also to cover the costs of study data collection.

Who has reviewed this study?

Before any research goes ahead it is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by North East - Newcastle & North Tyneside 2 Research Ethics Committee (Ref: 16/NE/0400). In addition, we have consulted with the Total Hip User Group, a patient user group for patients undergoing both hip and knee replacement and established for over 20 years, providing useful feedback on the study and this leaflet

I Would Like To Take Part in the Study…What Next?

If you decide to take part, we will discuss the study again with you face-to-face to ensure everything is clear and answer any questions you may have. We will then go through the study consent form with you.

What happens if something goes wrong?

This study only includes treatments that are already in routine practice. The clinicians treating you will take every opportunity to reduce risk. If something were to go wrong, they will offer the best possible solution to resolve it. If you have a concern about any aspect of this study, you should speak to us – our contact details can be found at the end of this document. If you are harmed by taking part in this study, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for legal action but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanism is available to you.

Who Can I Contact If I Have Any Questions?

If you need any further information, please contact us.

Mr Mike Reed, Consultant Trauma and Orthopaedic Surgeon at Wansbeck District General Hospital is in overall charge as Chief Investigator of the study and can be contacted on [add contact number].

The doctor who is involved with the day to day running of the study is Mr Jonny Kent. He can be contacted via the details below:

Mr Jonny Kent

Email – jonathan.kent1@nhs.net

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[add site specific contact details – Site PI and Site RN]

If you would like independent advice about whether or not to take part, the Patient Advice and Liaison Service (PALS) [or R&D] can be contacted on: XXXXXXXXX

We look forward to hearing from you.

Mr Jonny Kent
[Title]

Mr Mike Reed
Consultant Trauma and Orthopaedic Surgeon