**Patient Information Sheet**

**ROBOT; Reported Outcomes for Bandaging after Osteotomy Trial**

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information.

**Who is carrying out the study and why?**

The Chief Investigator for this study is Mr Matt Dawson, consultant Orthopaedic surgeon, working in collaboration with Dr Leon Jonker, Research & Innovation Manager at Cumbria Partnership NHS Foundation Trust. This study has been developed by NHS staff and is carried out in the Cumberland Infirmary and West Cumberland Hospital. The study will take place in a hospital setting with support and oversight from the treating orthopaedic surgeon (Dr Matt Dawson), nursing staff (including Ms Kirsty Robinson) and research staff. Where appropriate, research delivery staff will be delegated to provide support with data collection and processing.

The aim of this study is to determine the level of pain experienced by patients after osteotomy surgery and if there is a difference between two types of bandaging; non-compression bandaging and 3M Coban dual-layer-compression bandaging.

**Why have I been invited?**

You are being asked to participate in this research study because your clinical team have identified you as someone who is due to undergo high tibial osteotomy and the use of post-surgery bandaging of the affected leg is indicated.

**Do I have to take part?**

You do not have to take part; it is entirely up to you to decide whether you would like to be involved in our study. Take your time, discuss things with others and ask us about anything that is not clear or if you would like more information. Regardless of whether you decide to take part or not, your clinical treatment will not be affected by your decision. You are free to withdraw at any time without explanation and this will not affect the standard of care you receive in any way. If you withdraw at any stage of the study, then we will retain any study information collated up to that point.

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

If you decide that you may want to take part in the study, one of the research staff, which may be the chief investigator or a trained and delegated member of the study team, will take written consent from you. We ask permission to access your medical records to record data related to your knee osteotomy. We also ask permission to inform your GP of your participation in the study.

During your first appointment – prior to the osteotomy procedure, eg to coincide with your surgery pre-assessment clinic visit – we will take some additional measurements such as limb girth measurement and an ABPI measurement (ankle-brachial pressure index; measuring blood pressure in your legs and your arms to check if your blood circulation allows the use of compression bandaging). On the day of your surgery you will be allocated to either the **Control** **group** or the **Coban** **group**.

* **Control group**: you will receive current standard care non-compression bandaging (cotton wool and crepe bandaging over the wound site) for up to 48 consecutive hours.
* **Coban group**: you will receive Coban dual layer compression bandaging for up to twelve consecutive days.

You will be in the study for a period of 12 weeks, of which only the first 12 days are classed as the ‘intervention phase’. Thereafter, for the remainder of the 12 week period you will be followed up as you normally would in normal clinical practice.

*Figures 1 & 2. Standard wool and crepe bandaging (left) vs Coban dual layer compression bandaging device (right)*



You will be asked to complete four short questionnaires related to your knee osteotomy at five time points (see table 1). These questionnaires cover topics such as quality of life, pain experience, sleep and satisfaction regarding the bandaging. Some questionnaires are part of the regular management of osteotomy patients by Mr Dawson and his team (such as KOOS, Knee injury and Osteoarthritis Outcome Score, and OKS, Oxford Knee Score), and some questionnaire are additional for this specific study. The questionnaires will be done together with a member of the research team during your clinic appointments and will take approximately 5 to 10 minutes. Some additional questionnaires will be completed over the phone or via post or e-mail (whichever of the three you prefer). If, when you complete your quality of life questionnaire, we have any concerns then we will refer you to an appropriate service in order to safeguard your wellbeing.

**Table 1, Timeline and overview of different study visits**

|  |  |  |
| --- | --- | --- |
| **Type of visit** | **Point of contact** | **What will happen?** |
| **Visit 1#**  Pre-surgery  (<0 weeks) | Orthopaedics department | * Written Informed Consent * Collection of baseline information * Standard care questionnaires (KOOS, OKS, EQ5D-5L) * Study related questionnaires *(topics: sleep, quality of life)* * Limb girth and ABPI (blood pressure) measurement |
| **Visit 2#**  Day of surgery (day 0) | Orthopaedics department | * No research activity, apart from application of bandaging |
| Day 5 | Telephone/email/post | * Study related questionnaire *(topic: pain)* |
| **Visit 3#**  Day 12 | Orthopaedics department | * Study related questionnaires *(topics: pain, sleep, satisfaction)* * Limb girth measurement |
| Week 3 | Telephone/email/post | * Limb girth measurement |
| Week 6 | Telephone/email/post | * Study related questionnaires *(topics: pain, sleep, satisfaction)* |
| **Visit 4#**  Week 12 | Orthopaedics department | * Standard care questionnaires * Study related questionnaires *(topics: pain, quality of life, satisfaction)* |

**What are the possible benefits of taking part?**

For participants in the control group there is no direct benefit for taking part in this study. You will be cared for in exactly the same manner as you normally would, bar the introduction of a few questionnaires. However, by taking part you will contribute to comparison of the effectiveness of aftercare for osteotomy, to optimise management of knee osteoarthritis in the future. For participants in the Coban-group there may be benefits in terms of pain and swelling after the procedure. However, this has not yet been proven and established, and this study is aimed to assess this. There is no intended clinical benefit from taking part in this study. You cannot claim payments, reimbursement of expenses or any other benefits or incentives for taking part in this research.

**What are the possible disadvantages and risks of taking part?**

There is no personal safety risk anticipated regarding taking part in this study. Like with any invasive procedure, the osteotomy surgery carries (post-operative) risks such as bleeding, blood clots and infection. However, the osteotomy surgery itself is not classed as being part of this post-surgery ROBOT bandaging study and you will be asked to give separate written consent for the surgery itself. If you do decide to take part in the ROBOT study, and your surgeon, nurse or the research team learns of important new information that might affect your desire to remain in the study, they will tell you as soon as possible. Appropriate precautions are in place to ensure your medical and personal information is kept safe (see next sections).

**What will happen to the information that I give?**

All data will be held in secure environments in NHS Trusts. The requirements of the Data Protection Act and NHS Code of Confidentiality will be followed at all times. All researchers will be fully trained in NHS Confidentiality. Data released (e.g. by publication) will be anonymous; it will not contain any information that could lead to the identification of an individual participant. As part of providing a research grant for this study, we will share *anonymised* research data with 3M company (the manufacturer of the Coban two layer compression system), for which we will ask your written consent.

**Will my participation in the study be kept confidential?**

All your personal details will be treated as STRICTLY CONFIDENTIAL, in line with the Data Protection Act. Your data collected during your participation will be entered into a password-protected database and analysed – using only NHS computers and servers. None of your study data will be identified by your name – only by study number. Appropriate measures will be enforced to protect your identity in all presentations and publications, as required by United Kingdom regulations. The Sponsor’s clinical research staff, consultants, one or more nominated research organisation(s) working on behalf of Sponsor, Sponsor’s auditors or their representatives, the NHS representatives and regulatory authorities may have direct access to your medical records in order to make sure that the study is conducted correctly and to verify the results of the study. You authorise such direct access to your medical records by signing the informed consent form.

**What if something goes wrong?**

If you have any concerns at any stage of your involvement in this research project, please feel free to discuss these with the research team. We will do our best to resolve any problems quickly. If you are still unhappy and wish to complain about any aspect of the way you have been approached, the normal National Health Service (NHS) complaints mechanisms are available to you (Patient Experience Team contact details below).

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

Your participation in the study is voluntary. You can refuse to take part, or you can withdraw at any time. If you choose to withdraw, your clinician will continue treating you as he or she normally would and you do not have to give a reason as to why you wish to withdraw from the study. If you withdraw after signing the study consent form, you will not be able to re-enter the study. Any data collected up to the point where you withdraw will be retained for analysis as part of the study. The latter also applies if you were to lose capacity to take part during the study.

**Who is organising and funding the study?**

The study is organised by Orthopaedic Surgeon Mr Matt Dawson in collaboration with the Research Department of Cumbria Partnership NHS Foundation Trust. This NHS Trust is also the study sponsor for indemnity purposes. The study has been reviewed and approved by the National Ethics Research Service, Wales REC 7 committee, REC ref 18/WA/0027, the Health Research Authority and the NHS Trust (North Cumbria University Hospitals) where the study is conducted. The 3M Company is funding this study by means of an academic research grant.

The research team acts as a contact point and coordinator for patients requiring information and support. If concerns are raised, referral of patients/families on to other professional agencies will be done as appropriate and according to the Trust guideline.

**Contact for further information**

You can get more information or answers to your questions about the study, your participation in the study, and your rights, from the ROBOT research team:

* Name: Jose Schutter (research practitioner), Ms Kirsty Robinson (orthopaedic specialist nurse), and Mr Matt Dawson (orthopaedic surgeon)
* Phone number: 01228 814751 or 01768 245975
* Email: [Research@cumbria.nhs.uk](mailto:Research@cumbria.nhs.uk)

Generic information on taking part in clinical research can be obtained from the Patient Experience Team, tel 0800 633 5547 or [PET@cumbria.nhs.uk](mailto:PET@cumbria.nhs.uk) , or from websites such as the NHS Choices website, <http://www.nhs.uk/Conditions/Clinical-trials/Pages/Introduction.aspx>

***Thank you for taking the time to read this information sheet***