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Reported Outcomes for Bandaging after Osteotomy Trial

Submission date
19/03/2018

Recruitment status
No longer recruiting

Registration date
21/03/2018

Overall study status
Completed

Last Edited
10/08/2021

Condition category
Surgery

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Medial osteoarthritis (wearing of the inside of the knee joint) can be treated with medial wedge high tibial osteotomy (HTO for short). This procedure involves cutting the tibial bone (shinbone) and introducing an opening wedge to change the angle of the knee joint and thereby shift the patient's weight from the medial side (inside) to the lateral side (outside) of the knee. This then avoids the need for a partial or total knee replacement. As with other major knee operations, after surgery a lot of swelling can develop in and around the site of operation. This is painful, may increase the risk of surgical wound infection, and can limit a patient's progress with mobilisation after the operation. Therefore, research is already ongoing in the field of knee replacement surgery to determine if a different type of bandaging of the affected leg after surgery may improve patient and clinical outcomes. A new method is now available which involves bandaging that compresses the leg. This may reduce pain and swelling because fluid cannot build up as easily. This study aims to find out whether compression bandaging is better than standard non-compression bandaging in terms of keeping a patient comfortable by reducing pain, swelling and enabling early mobilisation.

Who can participate?
Patients aged over 18 undergoing HTO

What does the study involve?
Participants are randomly allocated to receive either standard bandaging or 3M Coban compression bandaging. Follow-up is up to 12 weeks after surgery. Incidence of infection and deep vein thrombosis/pulmonary embolism, readmission to hospital, pain, degree of swelling of the affected leg, and knee joint function are all assessed. The main objective is to see whether 3M Coban bandaging is significantly better than standard bandaging at day 12 after surgery.

What are the possible benefits and risks of participating?
For participants in the standard bandaging group there is no direct benefit for taking part in this study. Patients will be cared for in exactly the same manner as they normally would, apart from the introduction of a few questionnaires. However, by taking part they will help to improve the management of knee osteoarthritis in the future. For participants in the 3M Coban compression bandaging group there may be benefits in terms of pain and swelling after the procedure.

However, this has not yet been proven, and this study aims to assess this. There is no intended clinical benefit from taking part in this study. Patients cannot claim payments, reimbursement of expenses or any other benefits or incentives for taking part in this study. There is no personal safety risk anticipated regarding taking part in this study. Like with any invasive procedure, the osteotomy surgery carries risks such as bleeding, blood clots and infection after the operation. However, the osteotomy surgery itself is not classed as being part of this study and patients are asked to give separate written consent for the surgery itself. If they do decide to take part in the study, and their surgeon, nurse or the research team learns of important new information that might affect their desire to remain in the study, they will tell them as soon as possible. Appropriate precautions are in place to ensure medical and personal information are kept safe.

Where is the study run from?
North Cumbria University Hospitals NHS Trust (UK)

When is the study starting and how long is it expected to run for?
February 2018 to July 2019

Who is funding the study?
3M Deutschland GmbH (Germany)

Who is the main contact?
Dr Leon Jonker

Contact information

Type(s)
Scientific

Contact name
Dr Leon Jonker

ORCID ID
http://orcid.org/0000-0001-5867-4663

Contact details
Cumbria Partnership NHS Foundation Trust
R&D Department, Carleton Clinic
Carlisle
United Kingdom
CA1 3SX

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

37140

Study information

Scientific Title
A multi-centre, two-arm, controlled, prospective randomized trial of 3M Coban dual-layer compression bandaging versus non-compression bandaging after high tibial osteotomy surgery

Acronym
ROBOT

Study objectives
This study aims to assess if compression bandaging is better than standard non-compression bandaging in terms of keeping a patient comfortable by reducing pain, swelling and enabling early mobilisation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Wales REC 7, 06/02/2018, ref: 18/WA/0027

Study design
Randomised; Interventional; Design type: Treatment, Device

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
High tibial osteotomy

Interventions
A total of 68 patients will be recruited and allocated to either standard bandaging (34 patients) or 3M Coban compression bandaging (also 34 patients); follow-up of patients will be up to 12 weeks post-surgery. Apart from clinical outcomes data, such as incidence of infection and deep vein thrombosis/pulmonary embolism, plus readmission to hospital, patient-reported outcomes will be recorded too. These include pain experienced, degree of swelling of the affected leg, and knee joint functionality. The main objective of the study is whether 3M Coban bandaging is

significantly better than standard bandaging at day 12 post-surgery when measured on a visual display pain scale.

Intervention Type
Other

Primary outcome measure
Level of operation-site related pain experienced at day 12 post-operation and average pain scores in the control and Coban arm, measured using the 10 cm visual descriptor scale (VDS) for pain; Timepoint(s): End of the study

Secondary outcome measures
1. Post-operative patient-reported outcome measures are recorded using Visual Display Scale pain and short form McGill pain questionnaire at 5, 12 days, and 6, 12 weeks post-surgery
2. Quality of night rest measured by Richards-Campbell Sleep Questionnaire (two consecutive nights per timepoint) prior to surgery as baseline, and 12 days and 6 weeks post-surgery
3. Degree of swelling of affected limb recorded by measurement of thigh, suprapatellar and calf girth prior to surgery as control, and 12 days, 3 weeks post-surgery
4. Knee function and quality of life measured using the Knee and Osteoarthritis Outcome Score (KOOS), Oxford Knee Score (OKS), quality of life measured with EQ-5D-5L prior to surgery as baseline, and 12 weeks post-surgery
5. Descriptive safety overview obtained by recording readmissions to theatre and/or hospital, infection of wound site , and diagnoses of pulmonary embolism or deep vein thrombosis at 30 days and 12 weeks post-surgery

Overall study start date
01/02/2018

Completion date
30/07/2019

Eligibility

Key inclusion criteria
1. Patient who is listed for unilateral high tibial osteotomy using a fixed plate device at one of participating NHS Trusts
2. Clinical indication, in the opinion of the treating surgeon, that dual-layer compression bandaging may be of benefit to the patient
3. Adult patients aged > 18 years
4. Ankle brachial index measured within 12 weeks
5. Mental capacity to give written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 68; UK Sample Size: 68

Total final enrolment
49

Key exclusion criteria
1. Under the age of 18 years
2. Unable to fully understand the consent process and provide informed consent due to either language barriers or mental capacity
3. Revision high tibial osteotomy
4. Limited life expectancy, i.e. undergoing palliative care
5. Any condition that is associated with excessive bleeding, coagulation abnormalities or any other significant haematological condition (e.g. Factor V Leiden, haemophilia)
6. Cardiovascular or vascular condition that in the opinion of the treating surgeon contraindicates the use of compression bandaging, including moderate to severe peripheral arterial disease, venous leg ulcer, high dose anticoagulant medication
7. Any skin or other condition that contraindicates the use of compression bandaging, including diabetic foot ulcer and peripheral neuropathy
8. Patients who are participating in another interventional research study involving an investigational product related to the osteotomy procedure and its aftercare
9. The patient has concurrent (medical) conditions that in the opinion of the investigator may compromise patient safety or study objectives
10. Ankle brachial index < 0.8 or lack of foot pulses, measured within 12 weeks of surgery

Date of first enrolment
10/04/2018

Date of final enrolment
30/03/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
North Cumbria University Hospitals NHS Trust
Cumberland Infirmary
Orthopaedics Department
Newtown Road
Carlisle
United Kingdom
CA2 7HY

Sponsor information

Organisation
Cumbria Partnership NHS Foundation Trust

Sponsor details
R&D Department
Carleton Clinic
Carlisle
England
United Kingdom
CA1 3SX

Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Industry

Funder Name
3M Deutschland GmbH

Results and Publications

Publication and dissemination plan
The results of this study are planned to be disseminated through a peer-reviewed manuscript in scientific journal and internal report to the funder of the trial, 3M. A summary of the main findings can be supplied to participants on request and this will be stated in the informed consent form. All reporting is planned to be completed within one year of completion of the trial.

Intention to publish date
30/07/2020

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version v2	30/01/2018	21/03/2018	No	Yes
Protocol file	version v2	30/01/2018	21/03/2018	No	No
Results article		12/11/2020	10/08/2021	Yes	No
HRA research summary			28/06/2023	No	No