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Compression after surgery of the knee

Submission date
10/11/2021

Recruitment status
No longer recruiting

Registration date
17/11/2021

Overall study status
Completed

Last Edited
09/04/2024

Condition category
Surgery

[_] 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 either knee replacement or osteotomy procedures. With the former, either part or the whole of the knee joint is replaced. The latter involves cutting the tibial and or femoral bone and introducing an opening wedge to change the angle of the knee joint and thereby shift the patient's weight from the medial to the lateral side (outside) of the knee. With all major knee operations, the site of operation can be painful afterwards. Increased pain may limit a patient's progress with postoperative mobilisation. Therefore, research is already ongoing in the field of knee surgery to determine if different types 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. This study aims to assess whether compression bandaging is better than standard non-compression bandaging in terms of keeping a patient comfortable by reducing pain and possibly improving other clinical outcomes too.

Who can participate?
Patients aged over 18 years who are due to have surgery of the knee (knee replacement or osteotomy) and who are indicated to have bandaging applied to the leg after surgery.

What does the study involve?
On the day of knee surgery, patients will be randomly allocated to either the 'Control' group or the 'Andoflex' group. Those in the control group will receive current standard care non-compression bandaging (cotton wool and crepe bandaging over the wound site) for up to 48 consecutive hours. Those in the Andoflex group will receive Andoflex TLC Calamine Lite dual layer compression bandaging straight after surgery for five consecutive days. Other than the type of bandaging, other care will be as per usual clinical practice. Patients will be in the study for a period of 12 weeks, of which only the first 5 days are classed as the intervention phase. Thereafter, for the remainder of the 12-week period patients will be followed up as they normally would in normal clinical practice. Apart from clinical outcomes such as the degree and type of pain experienced by patients, safety data such as incidence of infection and deep vein thrombosis/pulmonary embolism, plus readmission to hospital will be recorded too.

What are the possible benefits and risks of participating?
For participants in the control group there is no direct benefit for taking part in this study. They will be cared for in exactly the same manner as they normally would, bar the introduction of a

few questionnaires. For participants in the Andoflex group there may be benefits in terms of pain after the procedure. However, this has not yet been proven and established, and this study is aimed to assess this. There are no major personal safety risks anticipated regarding taking part in this study. Bandaging itself can lead to some skin irritation and discomfort, and compression bandaging may affect blood flow if not applied correctly. Like with any invasive procedure, knee surgery carries (post-operative) risks such as bleeding, blood clots and infection. However, the surgical procedure itself is not classed as being part of this post-surgery bandaging study and patients will be asked to give separate written consent for the surgery itself.

Where is the study run from?
North Cumbria Integrated Care NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
February 2021 to October 2023

Who is funding the study?
Milliken Healthcare Inc. (USA)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
288969

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 50185, IRAS 288969

Study information

Scientific Title
A single-centre, two-arm, controlled, prospective randomized trial comparing standard crepe bandaging with Andoflex TLC Calamine Lite (25-30 mmHg) compression bandaging after knee surgery

Acronym
CASK

Study objectives
The main objective of the study is to find out whether Andoflex TLC Calamine Lite compression bandaging (worn for 5 days post-surgery) is significantly better than standard bandaging (worn for up to 48 hours post-surgery) at day 5 post-surgery when measured on a visual display pain scale.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 10/09/2021, Wales Research Ethics Committee 7 (Health and Care Research Wales, Castlebridge 4, 15-19 Cowbridge Road East, Cardiff, CF11 9AB, UK; +44 (0)2920 230457, +44 (0) 7920 565664; Wales.REC7@wales.nhs.uk), REC ref: 21/WA/0252

Study design
Randomized; Interventional; Design type: Treatment, Device, Rehabilitation

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Knee surgery

Interventions

Standard care (control) arm
As soon as the operation is finished and a wound dressing has been applied, the standard bandaging is applied. One layer of soft synthetic bandage, stretching from proximal tibia to distal femur covered by a further layer of crepe bandage prior to or after tourniquet deflation, with 50% overlap of each layer (cryotherapy can be applied over this if standard of care). The bandaging will be removed approximately 48 hours post-operatively whilst leaving the dressing in situ. The bandages can be removed sooner than 48 hours if the patients find them very uncomfortable or in the event of any adverse events that would require their removal.

Andoflex TLC Calamine Lite compression bandaging (intervention) arm
As with standard bandaging, the Andoflex TLC Calamine Lite compression bandage will be applied over the routine surgical wound dressing. A foam inner bandage (Andoflex TLC Calamine Lite 2, Milliken Healthcare) is applied from the toe to the groin on the affected leg with minimal overlap. The second layer, which is the actual compression bandage (Andoflex TLC Calamine Lite 2, Milliken Healthcare) is applied at full stretch and with a 50% overlap of bandage to ensure adequate compression in the application. The mode of action of this two-layer compressive bandage kit is of particular practical use, since it is tolerable for patients overnight due to its low resting pressure. Furthermore, it produces high-pressure compression with movement to stimulate the calf muscle pump. The bandage is applied from the toes upwards. The application of bandage from thigh to groin requires removal of the tourniquet first and so the leg is kept elevated until the bandaging is complete. There is a training video available on the correct application of the bandages: https://www.youtube.com/watch?v=pal0pY_cTRc (Andoflex is known as Coflex in some other countries such as the USA).

The compression bandage has been shown to affect compression for up to a week. To balance compression and comfort, patients are asked to continue wearing the bandage for 5 consecutive days after surgery. The bandages can be removed sooner if the patients find them very uncomfortable (which will be classed as an adverse event) or in the event of any other adverse events that would require their removal – this will be recorded on the Case Report Form and in medical notes. If requested by the patient, they are allowed to return to a hospital clinic to have the Andoflex TLC Calamine Lite bandaging reapplied if for any reason the first set needed to be taken off. To maintain consistency, clinical healthcare professionals who apply a new Andoflex TLC Calamine Lite bandage need to sign a declaration that they have watched the training video and are comfortable complying with the instructions. Full product information on the Coflex TLC Calamine two-layer compression system can be found on the Andover Healthcare Inc website https://andoverhealthcare.com/product/coflex-tlc-calamine/

There are two pressure options: compression of either (standard compression) 35-40 mmHg or (‘Lite’ compression) 25-30 mmHg, for patients with an ABPI of ≥0.8 or ≥0.5 respectively. Layer 1 is a soft foam roll impregnated with calamine that is designed to soothe and calm skin with multiple wounds or other skin conditions. Layer 2 is a non-latex short stretch compression bandage that sticks to itself and features Easy HandTear Technology, eliminating the need for scissors. Absorbs 20xs its dry weight vs. traditional Unna Boot, and 50% more active ingredients than traditional Unna Boot. It provides a two-step short stretch performance with high working pressure and low resting pressure. Visual indicators are provided for ease of application - ovals become circles when the intended compression is achieved.

Apart from the difference in the type of bandage, the protocol for the Andoflex TLC Calamine Lite arm is identical to that of the standard care group. Used bandaging will be disposed of in line with local guidelines on disposal of clinical waste if in clinical location, or by the patient in the home setting.

Intervention Type
Procedure/Surgery

Primary outcome measure
Pain (at rest) measured using the visual analogue score (VAS) at baseline, 3 days, 5 days, 12 days and 6 weeks

Secondary outcome measures
1. Pain (whilst walking) measured using the visual analogue score (VAS) at baseline, 3 days, 5 days, 12 days and 6 weeks
2. McGill pain profile measured using the visual analogue score (VAS) at baseline, 3 days, 5 days, 12 days and 6 weeks
3. Knee/limb range of motion measured using a goniometer at baseline and 6 weeks
4. Knee-specific pain profile measured using the KOOS score survey at baseline, 6 weeks and 12 weeks
5. Patient satisfaction with the bandaging measured using a non-validated survey at 12 days

Overall study start date
01/02/2021

Completion date
31/10/2023

Eligibility

Key inclusion criteria
1. Patient who is listed for:
1.1. Knee arthroplasty (replacement) surgery, either partial or total knee replacement (single or double)
1.2. Unilateral high tibial osteotomy (HTO) or distal femoral osteotomy (DFO) or a double osteotomy (HTO and DFO) at one of participating NHS Trusts
1.3, In case of double procedure patients, one leg will be classed as the index leg and all outcomes measures will focus on said leg
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. 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: 148; UK Sample Size: 148

Total final enrolment
122

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 of previous knee replacement or osteotomy on the index leg
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 anti-coagulant medication
7. Any skin or other condition that contraindicates the use of compression bandaging, including diabetic foot ulcer or peripheral neuropathy
8. Patients who are participating in another interventional research study involving an investigational product related to the knee 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

Date of first enrolment
06/10/2021

Date of final enrolment
31/07/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Cumberland Infirmary
Newtown Road
Carlisle
United Kingdom
CA2 7HY

Study participating centre
West Cumberland Hospital
Homewood Road
Whitehaven
United Kingdom
CA28 8JG

Sponsor information

Organisation
North Cumbria Integrated Care NHS Foundation Trust

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R&D Dept
Penrith
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CA11 8HX
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Sponsor type
Hospital/treatment centre

Website
https://www.ncic.nhs.uk/

ROR
https://ror.org/003hq9m95

Funder(s)

Funder type
Industry

Funder Name
Milliken Healthcare Products, LLC

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
30/04/2024

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be published as a supplement to the results publication.

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.1	31/08/2021	16/11/2021	No	Yes
Protocol file	version 1.1	31/08/2021	17/11/2021	No	No
Protocol file	version 1.2	20/04/2022	05/07/2022	No	No
HRA research summary			28/06/2023	No	No
Results article		05/04/2024	09/04/2024	Yes	No