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Knee replacement bandaging study (KReBS)

Submission date
20/02/2017

Recruitment status
No longer recruiting

Registration date
20/02/2017

Overall study status
Completed

Last Edited
02/05/2025

Condition category
Musculoskeletal Diseases

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
Total knee replacement (TKR) surgery is a common procedure where the weight bearing surfaces of the knee joint are replaced with metal and plastic components to relieve pain and disability. The most common condition which leads to the need for a TKR is osteoarthritis (a type of arthritis where the surface of joints wears away, causing pain and stiffness). Swelling around the knee is commonly seen after a patient has had TKR surgery, and is thought to contribute to pain after surgery and slowing down the rehabilitation process. Inelastic compression bandages (tight-fitting bandages) are routinely used in the treatment of a range of conditions, including leg ulcers and lymphedema (a long-term condition that causes swelling in the body's tissues). Their use in helping reduce swelling is not well documented but it is thought that they aid venous blood return to the heart whilst improving the efficacy of the calf muscles which work as pumps to help return blood and thus help swelling. The aim of this study is to investigate whether use of short stretch inelastic compression bandages can help to reduce pain and swelling after TKR surgery. Blood loss during and following total knee replacement reduces a patient's haemoglobin and haematocrit counts whilst also increasing the need for a transfusion. By controlling the bleeding and subsequent swelling it is also thought that pain after surgery can be reduced. The study also assesses whether the use of a compression bandage will help reduce blood loss.

Who can participate?
Adults who are having a total knee replacement at a participating hospital

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive standard care. This involves application of a cotton wool bandage and crepe following knee replacement. Those in the second group have a compression bandage applied from the foot up to the groin. In both groups, the bandages will be applied in theatre and left in place for up to 48 hours before they are discharged from hospital. At the start of the study and then again after six and twelve months, participants complete a range of questionnaires and assessment to find out how well their knee has recovered after surgery. Participants in Northumbria NHS Foundation Trust also have their routinely taken full blood counts and blood transfusion data collected, and acute pain is assessed through pain scores routinely taken before and after surgery along with their analgesic (painkiller) requirements.

What are the possible benefits and risks of participating?
Participants who receive the compression bandages could benefit from decreased swelling and pain after surgery and ultimately better knee function and outcome. There are no notable risks involved with participating.

Where is the study run from?
Northumbria Healthcare NHS Foundation Trust and 14 other NHS trusts throughout the UK (UK)

When is the study starting and how long is it expected to run for?
August 2016 to November 2020

Who is funding the study?
3M Company (USA)

Who is the main contact?
Mrs Elizabeth Cook
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Study website
https://www.york.ac.uk/healthsciences/research/trials/research/trials/krebs/

Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
32352

Study information

Scientific Title
A randomised controlled trial of the effect of a two-layer compression bandage system on knee function following total knee arthroplasty

Acronym
KReBS

Study objectives
The aim of this study is to assess the effectiveness and cost-effectiveness of a two-layer compression bandage worn post-operatively for up to 48 hours, compared to standard practice (non-compressive bandaging) on patient reported outcomes following elective total knee replacement.

Substudy added 22/02/2018:
A substudy is being undertaken as part of a student project that will be reported separately to the main trial. In this substudy it is hypothesised that the use of a compression bandage will act as a tamponade and help reduce blood loss.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North East - Newcastle & North Tyneside 2 Research Ethics Committee, 08/02/2017, ref: 16/NE/0400

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
Specialty: Musculoskeletal disorders, Primary sub-specialty: Elective Orthopaedic Surgery; UKCRC code/ Disease: Musculoskeletal/ Other joint disorders

Interventions
Participants are randomised to one of two groups via a secure internet system utilising a simple randomisation process.

Control group: Participants receive crepe bandage and synthetic wool layer for up to 48 hours post TKR proximal shin to distal thigh following adhesive dressing application in theatre.

Intervention group: Participants receive a 2 layer Compression bandage (Coban 2 3M) for 48hrs post TKR from foot to groin following adhesive dressing application in theatre.

Standard post knee replacement surgery care for both arms following bandage application. Both arms will have standard hospital led follow up. In addition, Oxford knee score and EQ 5D questionnaires will be sent to patients at six and 12 months respectively as well as SMS text messages for VAS at 10 days, 4 weeks and 12 months post TKR.

Substudy added 22/02/2018:
Following recruitment into the main study, those patients undergoing total knee replacement in Northumbria NHS Foundation Trust will also have their routinely taken pre and post-operative full blood counts and transfusion data reviewed. Acute pain will also be assessed through routinely taken pre and post-op pain scores and analgesic requirements.

Intervention Type
Other

Phase
Phase III

Primary outcome measure
Patient reported knee function and pain is measured using the Oxford Knee Score at baseline (pre-operatively), 12 months post-operatively

Substudy added 22/02/2018:
Haemoglobin drop: difference between pre-op at pre-assessment or anaemia clinic and day 1 post-op levels

Secondary outcome measures
1. Patient reported knee function and pain is measured using the Oxford Knee score at baseline (pre-operatively) and 6 months posy-operatively
2. Health related quality of life is measured using the EQ-5D-3L at baseline (pre-operatively), 6 and 12 months post-operatively.
3. Health related quality of life is measured using the EQ-5D-5L at baseline (pre-operatively) and 12 months post-operatively- the validity and responsiveness of EQ5D-5L will be compared against EQ5D-3L. The UK value sets for the EQ-5D-5L are currently being derived and analysis will follow the most recent EuroQol guidance.
4. Pain is measured by VAS at 10 days post-operatively, 4 weeks and 12 months post-operatively
5. Proportion of each patient group that have to return to theatre within 30 days of surgery for any reason is assessed by hospital episode statistics at 12 months post-operatively
6. Proportion of each patient group that is readmitted to hospital within 30 days of surgery for any reason is assessed using local NHS trust patient administration system (PAS) data at 12 months post-operatively
7. Proportion of each patient group that suffers a pulmonary embolism requiring in patient hospitalization within 30 days post-operatively is assessed using local NHS trust patient administration system (PAS) data at 12 months post-operatively
8. Proportion of each patient group that suffers a deep vein thrombosis requiring inpatient hospitalization within 30 days of surgery is assessed using local NHS trust patient administration

system (PAS) data at 12 months post-operatively
9. Length of hospital stay will be calculated and assessed by using admission and discharge dates

Substudy added 22/02/2018:
1. Haematocrit drop: difference between pre-op at pre-assessment or anaemia clinic and day 1 post-op levels
2. Transfusion rate: units of Red blood cell transfusion as inpatient
3. Length of stay: nights spent as inpatient during acute stay
4. Analgesic requirements: cumulative dose for analgesia whilst an inpatient from patient records
5. Pain score: day 1 post op pain using 1-10 pain scale as recorded by nursing staff and day 10 pain scores via SMS and a pain scale 1-10

Overall study start date
01/08/2016

Completion date
07/11/2020

Eligibility

Key inclusion criteria
1. Patients scheduled for primary total knee arthroplasty
2. Presenting at a participating trial site
3. Aged over 18
4. Able to provide written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 2600; UK Sample Size: 2600

Total final enrolment
2338

Key exclusion criteria
1. Unable to consent
2. History of peripheral vascular disease
3. History of peripheral neuropathy
4. History of, or current venous ulceration
5. Absent foot pulses

6. Planned same day discharge joint replacement patients
7. Revision knee arthroplasty
8. Unicondylar or patellofemoral joint knee arthroplasty
9. Regular concomitant high dose anti-coagulant medication. Patients on routine thromboprophylaxis can be included
10. Unwilling to provide informed consent
11. Lack mental capacity and therefore unlikely to comply with data collection

Date of first enrolment
01/03/2017

Date of final enrolment
31/08/2018

Locations

Countries of recruitment
United Kingdom

Study participating centre
Betsi Cadwalder University Health Board
-
United Kingdom
-

Study participating centre
City Hospitals Sunderland NHS Foundation Trust
-
United Kingdom
-

Study participating centre
County Durham and Darlington NHS Foundation Trust
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United Kingdom
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Study participating centre
Dorset County Hospital NHS Foundation Trust
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United Kingdom
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Study participating centre
East and North Hertfordshire NHS Trust
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United Kingdom
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Study participating centre
East Kent Hospitals University NHS Foundation Trust
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United Kingdom
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Study participating centre
Gateshead Health NHS Trust
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United Kingdom
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Study participating centre
Golden Jubilee National Hospital
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United Kingdom
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Study participating centre
Hampshire Hospitals NHS Foundation Trust
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United Kingdom
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Study participating centre
Maidstone and Tunbridge Wells NHS Trust
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United Kingdom
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Study participating centre
Norfolk and Norwich University Hospital
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United Kingdom
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Study participating centre
North Cumbria University Hospitals NHS Foundation Trust
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United Kingdom
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Study participating centre
North Tees and Hartlepool NHS Foundation Trust
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United Kingdom
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Study participating centre
Northumbria Healthcare NHS Foundation Trust
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United Kingdom
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Study participating centre
Royal Devon and Exeter NHS Foundation Trust
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United Kingdom
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Study participating centre
Royal Devon and Exeter NHS Foundation Trust
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United Kingdom
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Study participating centre
South Tees Hospitals NHS Foundation Trust
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United Kingdom
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Study participating centre
Stockport NHS Foundation Trust
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United Kingdom
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Study participating centre
Taunton and Somerset NHS Foundation Trust
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United Kingdom
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Study participating centre
The Dudley Group NHS Foundation Trust
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United Kingdom
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Study participating centre
University Hospital of South Manchester NHS Foundation Trust
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United Kingdom
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Study participating centre

Warrington and Halton Hospitals NHS Foundation Trust
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United Kingdom
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Study participating centre
Western Sussex Hospitals NHS Foundation Trust
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United Kingdom
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Study participating centre
Wrightington, Wigan and Leigh NHS Foundation Trust
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United Kingdom
-

Study participating centre
York Teaching Hospital NHS Foundation Trust
-
United Kingdom
-

Sponsor information

Organisation
Northumbria Healthcare NHS Foundation Trust

Sponsor details
Wansbeck Hospital
Woodhorn Lane
Ashington
England
United Kingdom
NE68 6JJ
+44 (0)344 811 8111
contactus@northumbria.nhs.uk

Sponsor type
Hospital/treatment centre

Website
https://www.northumbria.nhs.uk/our-locations/wansbeck-general-hospital

ROR
https://ror.org/01gfeyd95

Funder(s)

Funder type
Industry

Funder Name
3M

Alternative Name(s)
3M Company, 3M Science Applied to Life, 3M Science. Applied to Life. 3M United States, Minnesota Mining and Manufacturing Company

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Publication and dissemination plan
Exact plans unknown but planned publication in a high-impact peer reviewed journal.

Intention to publish date
31/12/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from David.Torgerson@york.ac.uk

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Participant information sheet	version V1	05/01/2017	21/02/2017	No	Yes
Protocol article	protocol	08/05/2019	10/05/2019	Yes	No
Basic results			06/09/2022	No	No
Other publications	An embedded randomised controlled retention trial of personalised text messages compared to non-personalised text messages in an orthopaedic setting	11/06/2020	31/10/2022	Yes	No
HRA research summary			28/06/2023	No	No
Results article		05/07/2024	02/05/2025	Yes	No