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The use of compression bandages in total knee replacement surgery

Submission date
12/02/2013

Recruitment status
No longer recruiting

Registration date
30/05/2013

Overall study status
Completed

Last Edited
11/12/2018

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 (both sides of your knee joint are replaced with an artificial joint) 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 best possible care before, during and after surgery. This involves many members of the healthcare team and ensuring that you have effective pain relief and are mobilised as early as possible, to make 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 the surgery. However, these findings have not yet been proven in a large, well-designed scientific study. The long-term aim is to investigate whether compression bandages worn after knee replacement surgery improves knee swelling, stiffness and early function compared to normal dressings. As a large trial will be required to answer this question, the initial aim is to determine the feasibility of our study design for a larger future study.

Who can participate?
Patients (male and female) with osteoarthritis who are on the waiting list for primary total knee replacement at Wansbeck District General Hospital can participate. You must be over 18 and be able to give written informed consent.

What does the study involve?
We hope to enrol approximately 50 patients for the study. If you decide to be involved with the study, you will be selected at random to receive either the compression bandage or the standard bandage after surgery. This is done at random to try and eliminate any biases in the study. You have to receive one or the other so that we can see if the compression bandage makes a

difference to what we are doing already. During your hospital stay, in addition to normal management, pain scores, knee swelling and range of motion will be measured before and daily after your surgery. These factors will also be assessed at your routine six week follow-up clinic.

What are the possible benefits and risks of participating?
Possible benefits include reduce post-operative pain, swelling and an improved range of motion. We hope this will increase patient satisfaction and outcome. We do not foresee any disadvantages taking part in the study. There is a small chance of discomfort 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.

Where is the study run from?
The study is being co-ordinated and taking place at Wansbeck District General Hospital, Ashington (Northumbria NHS trust).

When is the study starting and how long is it expected to run for?
Recruitment is expected to start in September 2013 and will last for six months in total.

Who is funding the study?
The study is being funded by Northumbria NHS Trust.

Who is the main contact?
Dr Tim Brock
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Contact information

Type(s)
Scientific

Contact name
Mr Mike Reed

Contact details
Wansbeck District Hospital
Woodhorn Lane
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Ashington
United Kingdom
NE68 6JJ

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1

Study information

Scientific Title
A prospective, controlled, feasibility study investigating the use of a two-layer, short-stretch compression bandage in elective total knee replacement

Study objectives
The use of compression bandages worn after total knee replacement will aid rehabilitation through decrease pain and swelling, and improved range of motion.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Newcastle and North Tyneside REC ethics committee, ref: 13/NE/0137

Study design
Randomised controlled feasibility study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Osteoarthritis/total knee replacement

Interventions
Patients will be randomised to receive either a two-layer compressive dressing or a conventional dressing applied immediately post-operatively in theatre. The two-layer compressive dressing will consist of an inner layer of soft padding (Soffban, BSN Medical Ltd, Brierfield, UK) surrounded by a layer of short stretch compressive bandage (Actico bandage, Activa Healthcare Ltd, UK) applied firmly from toes to mid-thigh.

The conventional dressing will consist of a layer of inner soft padding (Soffban, BSN Medical Ltd, UK) with an outer layer of crepe bandage (BSN Medical Ltd, UK) applied around the knee. The

bandages will be taken off at 24 hours post-operatively. Standard total knee replacement protocol will be otherwise followed.

Measurements in each arm to include:
1. Swelling (circumference at mid-thigh, mid-patella and mid-leg in comparison to pre-op limb measured pre-operatively, 24 hours post-operatively, every day until discharge, 6 weeks)
2. Range of Motion (goniometer, measured pre-operatively, 24 hours post-operatively, every day till discharge, 6 weeks)
3. Pain (visual analogue scale 1-10 immediately post-op, before and after physiotherapy, every day till discharge)
4. Analgesia use (morphine used in 48 hours/kg)
5. Blood loss [pre-operative haemoglobin (Hb) and post-operative Hb at 48 hours, any blood transfusion required)
6. Length of stay (days)
7. Function (Oxford knee score questionnaire pre-operatively, 6 months as standard practice)
8. Patient satisfaction (EQ5D health status questionnaire pre-operatively, 6 months as standard practice)
9. Adverse events (6 weeks; surgical site infection questionnaire, documented evidence of cardiovascular, urinary, neurological complication, deep vein thrombosis [DVT], pulmonary embolism [PE] from records)

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The aim of this feasibility study is to estimate rates of patient recruitment, randomisation, retention and response, logistics of trial methodology, and resource utilisation.

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/09/2013

Completion date
01/03/2014

Eligibility

Key inclusion criteria
1. Male and female over 18 years
2. Selected for total knee replacement

Participant type(s)
Patient

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
50

Key exclusion criteria
1. Extensive peripheral vascular disease
2. Extensive small vessel disease
3. Lower limb neurological disorder

Date of first enrolment
01/09/2013

Date of final enrolment
01/03/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Wansbeck District Hospital
Ashington
United Kingdom
NE68 6JJ

Sponsor information

Organisation
Northumbria Healthcare NHS Foundation Trust (UK)

Sponsor details
Wansbeck Hospital
Woodhorn Lane
Ashington
England

United Kingdom
NE68 6JJ

Sponsor type
Hospital/treatment centre

Website
http://www.northumbria.nhs.uk/

ROR
https://ror.org/01gfeyd95

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Northumbria Healthcare NHS Foundation Trust (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	11/03/2015		Yes	No
Results article	results	09/01/2017		Yes	No
HRA research summary			28/06/2023	No	No