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Safety and feasibility evaluation of tourniquets for total knee replacement study

Submission date
17/02/2016

Recruitment status
No longer recruiting

Registration date
17/02/2016

Overall study status
Completed

Last Edited
25/01/2021

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
The majority of surgeons perform total knee replacement surgery with the aid of a tourniquet. The tourniquet interrupts the blood supply and drainage from the leg and helps to create a bloodless area for the surgery to take place. A tourniquet may however increase a patients' risk of developing a blood clot. At the end of surgery the tourniquet is deflated and blood clots that may have accumulated in the leg are immediately free to flow (embolise) within the blood stream. In some cases, blood clots and debris can return to the heart where they are then free to travel to the brain. This risk has never been examined with any definitive clinical study and it's not known if such a study would even be feasible. This is what this study is investigating.

Who can participate?
Adults about to have a total knee replacement at University Hospitals Coventry and Warwickshire NHS trust.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in group 1 have their total knee replacement surgery with a tourniquet. Those in group 2 have their surgery without a tourniquet. They all have a magnetic resonance (MR) imaging scan of their brain before having surgery and afterwards to look for evidence of clots and debris in the brain. Some participants and surgeons taking part in the study are also invited to take part in an interview to discuss their views and opinions of the of the study and how acceptable they find it. Participants are also followed-up within a year of their surgery when they are asked about how much knee pain they are experiencing and the how well the replacement joint is functioning. The researchers involved in this study also collect data from an existing database of total knee replacement surgery in England and Wales (National Joint Registry-NJR) and map it to other existing databases of deaths and hospital reported blood clots.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
University Hospitals Coventry and Warwickshire NHS trust

When is the study starting and how long is it expected to run for?
January 2017 to June 2018

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Mr Peter Wall

Contact information

Type(s)
Public

Contact name
Mr Peter Wall

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Additional identifiers

Protocol serial number
20280

Study information

Scientific Title
Safety and feasibility evaluation of tourniquets for Total Knee Replacement (SAFE-TKR): A pilot feasibility study

Acronym
SAFE--TKR

Study objectives
Current study hypothesis as of 08/10/2018:
This is a study designed to determine if a full randomised controlled trial comparing clinical outcomes following total knee replacement (TKR) surgery with or without a tourniquet is feasible

Previous study hypothesis:
This is a pilot trial investigating whether a full randomised controlled trial comparing the risk of blood clots developing after total knee replacement (TKR) surgery for patients that have a tourniquet applied during surgery verses those that do not is feasible.

Ethics approval required
Old ethics approval format

Ethics approval(s)
West Midlands - Edgbaston Research Ethics Committee, 16/12/2015, ref: 15/WM/0455

Primary study design
Interventional

Study design
Interventional and Observational; Design type: Treatment, Qualitative

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Musculoskeletal disorders, Surgery; Subtopic: Musculoskeletal (all Subtopics), Surgery; Disease: Elective Orthopaedic Surgery, All Surgery

Interventions
This feasibility study will comprise of three parts:
1. Patients due for TKR surgery will invited to take part in a pilot trial and randomised to surgery with or without a tourniquet with a view to recruiting 50 patients. All patients will undergo a Magnetic Resonance (MR) imaging scan of their brain before and after surgery to look for evidence of clots and debris in the brain. Other potentially important outcomes including knee pain and function within 12 months will also be collected.
2. Integrated qualitative research study. An interview study of around 30 patients and around 20 surgeons will capture the views and opinions of both groups regarding the acceptability of the pilot trial.
3. Retrospective multi-centre cohort study. A study of an existing database of TKR surgery in England and Wales (National Joint Registry-NJR) will be undertaken. The data will be mapped to other existing databases of deaths and hospital reported blood clots.

Intervention Type
Other

Primary outcome(s)
Primary outcome as of 04/05/2017:
Total volume of acute brain lesions detected on Magnetic Resonance (MR) brain imaging per patient, day 1 or 2 post operatively.

Original primary outcome:
Total volume of acute brain lesions detected on Magnetic Resonance (MR) brain imaging per patient, day 1 post operatively

Key secondary outcome(s)

Current secondary outcome measures as of 08/10/2018:
1. Montreal Cognitive Assessment (MoCA) preoperatively and day 1, 2 and 7 days post operatively and 6 and 12 month post operatively.
2. Oxford Cognitive Screen (OCS) preoperatively and day 1, 2 and 7 post operatively
3. Mini-mental state examination (MMSE) scores preoperatively and on day 1, 2 and 7 post operatively
1. Knee pain is measured using the Oxford Knee Score post operatively at baseline, 1 week, 6 and 12 month
2. Thigh pain is measured using the Visual Analogue Score (VAS) for acute thigh pain at baseline, day 1, day 2 and 1 week
3. Knee pain is measured using the EQ-5D-5L at baseline, 1 week, 6 and 12 months
4. Number of symptomatic VTE events is measured by questionnaire up to 12 months post operatively
5. Surgical Complication rate is measured by questionnaire up to 12 month post operatively
6. Number of intra/post-operative blood transfusions are measured by patient notes up until discharge
7. Revision rate of the TKR prosthesis is measured by questionnaire or patient notes at 12 months
8. All-cause mortality rates are measured by patient notes or next of kin at 12 months
9. Change in haemoglobin concentration between pre-operative haemoglobin and post operative haemoglobin

Previous secondary outcomes as of 04/05/2017:
1. Knee pain is measured using the Oxford Knee Score post operatively at baseline, 1 week, 6 and 12 month
2. Thigh pain is measured using the Visual Analogue Score (VAS) for acute thigh pain at baseline, day 1, day 2 and 1 week
3. Knee pain is measured using the EQ-5D-5L at baseline, 1 week, 6 and 12 months
4. Number of symptomatic VTE events is measured by questionnaire up to 12 months post operatively
5. Surgical Complication rate is measured by questionnaire up to 12 month post operatively
6. Number of intra/post-operative blood transfusions are measured by patient notes up until discharge
7. Revision rate of the TKR prosthesis is measured by questionnaire or patient notes at 12 months
8. All-cause mortality rates are measured by patient notes or next of kin at 12 months

Original secondary outcomes:
1. Montreal Cognitive Assessment (MoCA) preoperatively and day 1, 2 and 7 post operatively
2. Oxford Cognitive Screen (OCS) preoperatively and day 1, 2 and 7 post operatively
3. Mini-mental state examination (MMSE) scores preoperatively and on day 1, 2 and 7 post operatively
4. Oxford knee score (OKS) preoperatively and at 6 and 12 months postoperatively
5. EuroQol (EQ-5D-5L) scores preoperatively and at 6 and 12 months postoperatively
6. Number of symptomatic VTE events up to 12 months postoperatively.
7. Type and frequency of all adverse and serious adverse events up to 12 months postoperatively
8. Number of intra/post-operative blood transfusions until discharge
9. Revision rate of the TKR prosthesis at 12 months
10. All cause mortality rates at 12 months

Completion date
31/01/2019

Eligibility

Key inclusion criteria
Inclusion criteria as of 04/05/2017:
1. Patients must be aged 18 years and over
2. Patient is undergoing primary unilateral knee replacement
3. The patient is able to give written informed consent and participate fully in the trial interventions and follow up procedures

Original inclusion criteria:
1. All patients undergoing an elective primary unilateral cemented total knee replacement (TKR) under the care of four orthopaedic consultants at University Hospitals Coventry and Warwickshire (UHCW) NHS trust
2. Male and Female
3. Lower age limit 18 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
53

Key exclusion criteria
Exclusion criteria as of 04/05/2017:
1. Patients for whom Magnetic Resonance (MR) imaging is contraindicated due to
1.1. None compliant heart pacemaker or defibrillator
or
1.2. None compliant metallic foreign body e.g. in one or both eyes or aneurysm clips in the brain
or
1.3. Claustrophobia (e.g. difficulty in an elevator or telephone box)
2. Patients not suitable for a thigh tourniquet (e.g. significant peripheral vascular disease)
3. Previous participation in the SAFE-TKR Trial

Original exclusion criteria:
1. Patients who lack capacity under the Mental Capacity Act 2005

2. Patients for whom Magnetic Resonance (MR) imaging is either contraindicated (heart pacemaker, metallic foreign body in one or both eyes, or who have an aneurysm clip in their brain) or not feasible because of claustrophobia

Date of first enrolment
07/04/2017

Date of final enrolment
01/03/2018

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Warwick
Clinical Sciences Research Institute
Clinical Sciences Building
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Study participating centre
University Hospitals Coventry and Warwickshire NHS trust
Clifford Bridge Rd
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Sponsor information

Organisation
University of Warwick

ROR
https://ror.org/01a77tt86

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	22/01/2021	25/01/2021	Yes	No
Protocol article	protocol	10/04/2018	30/11/2020	Yes	No
HRA research summary			28/06/2023	No	No