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Perioperative Analgesia for Knee Arthroplasty

Submission date	Recruitment status	[X] Prospectively registered
08/11/2013	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
08/11/2013	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
13/08/2019	Musculoskeletal Diseases	

Plain English summary of protocol

Background and study aims
The aim of this study is to find out if there is a difference in pain prior to physiotherapy on the first day after the operation between patients who are given local knee injections following a total knee replacement, compared to the standard treatment (femoral nerve block). Another aim of this study is to assess the function and health outcome of the study group at 6 weeks after the operation.

Who can participate?
All patients undergoing a total knee replacement surgery under the care of an orthopaedic consultant at the University Hospitals Coventry and Warwickshire NHS Trust, UK.

What does the study involve?
Patients will be randomly allocated to receive either local knee injections or standard treatment. On the first and second day after the operation, participants will be asked to rate their pain in and around their knee before and after physiotherapy. In addition, patients will be followed up at 6-8 weeks after the operation.

What are the possible benefits and risks of participating?
There are no specific advantages to you taking part in the study. However, the information we get from this study may help up to choose the best type of pain relief for patients having the same sort of surgery as you in the future.

Where is the study run from?
Warwick Orthopaedics, University of Warwick, UK.

When is the study starting and how long is it expected to run for?
The study will begin recruiting in December 2013 for 24 months.

Who is funding the study?
The study is being funded by the National Institute for Health Research (NIHR) (UK).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2013-002439-10

ClinicalTrials.gov (NCT)
NCT01560767

Protocol serial number
15232

Study information

Scientific Title
Perioperative Analgesia for Knee Arthroplasty: a prospective randomised controlled trial

Acronym
PAKA

Study objectives
Arthritis of the knee is a common problem; it causes inability to walk without pain and a reduction in activity levels. Total knee replacements are performed for relief of this debilitating pain and are the most common form of joint replacement performed within the NHS. Increased demand for total knee replacement, together with an ageing population, has led to an annual increase in frequency of this form of replacement. The operation involves removing worn-out surfaces and replacing them with implants.

Knee replacement generates substantial amounts of postoperative pain, which affects range of movement and ability to mobilise. It is important that good pain relief is administered post-operatively to enhance patient rehabilitation. Current pain relief targets large groups of nerves, paralysing areas of the body of limb. Recently, the use of injections around the knee has gained in popularity. These injections have the advantage of delivering drugs directly to the sources of pain, thereby avoiding side effects in the rest of the body. They contain different analgesics, such as local anaesthetics, opiates and non-steriodal anti-inflammatory drugs. Some of the theorectical advantages include reduced requirements for painkillers after the operation, and earlier mobilisation, discharge and better overall outcome following knee surgery.

We propose to perform a single-centre patient-based randomised controlled trial of local knee injections (peri-articular infiltration) versus standard treatment (femoral nerve block) with pain as the primary outcome measure. In preparation for this study we have performed a pilot study recruiting 46 patients which has supplied us with the data required to plan this full trial.

Ethics approval required
Old ethics approval format

Ethics approval(s)
13/WM/0316; First MREC approval date 23/09/2013

Study design
Randomised; Interventional; Design type: Not specified, Treatment

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Musculoskeletal; Subtopic: Musculoskeletal (all Subtopics); Disease: Musculoskeletal

Interventions
Femoral Nerve Block, Standard femoral nerve block; Periarticular infiltration, A multi-modal peri-articular knee infiltration; Follow Up Length: 2 month(s); Study Entry: Single Randomisation only

Randomisation will be stratified between general anaesthetic and spinal block.

Data will be collected at the follow time points: baseline, day 1 and day 2 post-operation, 6 weeks post operation

Intervention Type
Procedure/Surgery

Primary outcome(s)
Visual Analogue Scale; Timepoint(s): Pre-physiotherapy on the first post-operative day

Key secondary outcome(s))
1. As required analgesia; timepoint(s): the total use of as required analgesia in the first 48 hours after the operation

2. Bed transfers; timepoint(s): day 1 and 2 postoperatively
3. Distance mobilised; timepoint(s): day 1 and 2 postoperatively
4. EQ-5D-5L; timepoint(s): baseline and 6 weeks postoperatively
5. Knee range of movement; timepoint(s): day 1 and 2 postoperatively
6. Ordinal Pain Score; timepoint(s): routinely collected by nursing staff every 6 hours for the first 48 hours following surgery
7. Oxford Knee Score; timepoint(s): baseline and 6 weeks postoperatively
8. Routine physio assessments
9. Bed transfers and distance mobilised
9. Straight leg raise; timepoint(s): day 1 and 2 postoperatively
10. Timed up and go; timepoint(s): day 1 and 2 postoperatively

Completion date
31/10/2015

Eligibility

Key inclusion criteria
All patients undergoing an elective primary unilateral total knee arthroplasty under the care of an orthopaedic consultant at University Hospitals Coventry and Warwickshire NHS Trust.
Target Gender: Male & Female ; Lower Age Limit 18 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. A concomitant medical or psychiatric problem which, in the opinion of the Investigator, would prevent completion of treatment or follow-up
2. Patients with a preoperative history of neurological abnormality in the ipsilateral leg
3. Patients with specific contraindication to the analgesic agents used
4. Participation in a clinical trial of an investigational medicinal product in the last 90 days
5. Previous entry in the present trial

Date of first enrolment
01/12/2013

Date of final enrolment
31/10/2015

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University Hospitals Coventry & Warwickshire NHS Trust
Coventry
United Kingdom
CV2 2DX

Sponsor information

Organisation
University Hospitals Coventry & Warwickshire NHS Trust (UK)

ROR
https://ror.org/025n38288

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research Central Commissioning Facility; Grant Codes: PB-PG-0212-27098

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date

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	01/07/2017		Yes	No
Protocol article	protocol	21/12/2015		Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes