

Perioperative Analgesia for Knee Arthroplasty

Submission date 08/11/2013	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 08/11/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 13/08/2019	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

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?

Mr Peter Wall
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Contact information

Type(s)

Scientific

Contact name

Mr Peter Wall

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Additional identifiers

EudraCT/CTIS number

2013-002439-10

IRAS number

ClinicalTrials.gov number

NCT01560767

Secondary identifying numbers

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-steroidal anti-inflammatory drugs. Some of the theoretical 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

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 of C.A.Lawrence below to request a patient information sheet

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 measure

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

Secondary outcome measures

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

Overall study start date

30/09/2013

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned Sample Size: 264; UK Sample Size: 264

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**

England

United Kingdom

Study participating centre

University Hospitals Coventry & Warwickshire NHS Trust

Coventry

United Kingdom

CV2 2DX

Sponsor information**Organisation**

University Hospitals Coventry & Warwickshire NHS Trust (UK)

Sponsor details

Clinical Sciences Research Unit

Clinical Sciences Building

Clifford Bridge Road

Coventry

England

United Kingdom

CV2 2DX

Sponsor type

Hospital/treatment centre

ROR

Funder(s)

Funder type

Government

Funder Name

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

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

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?
Protocol article	protocol	21/12/2015		Yes	No
Results article	results	01/07/2017		Yes	No
HRA research summary			28/06/2023	No	No