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Post operative pain relief following knee replacement

Submission date	Recruitment status	[_] Prospectively registered
16/02/2012	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
06/06/2012	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
14/02/2019	Surgery	

Plain English summary of protocol

Background and study aims
The aim of this study is to help us better understand the ways in which we can manage pain in patients who have had a knee replacement. There are various methods of pain relief; all of these treatments have been shown to work well. Currently, the treatment depends on the surgeons preference. This project will compare two methods of pain relief to see if patients experience less pain and are more mobile, with one method above another.

Who can participate?
Any patient due to undergo a total knee replacement at the Lancashire Teaching Hospital

What does the study involve?
Patients will be randomly put into one of the two groups, and each group will receive a different method of pain relief to cover the period following the operation. One group will be given a femoral nerve block, which is a type of local anaesthetic which numbs the area of the thigh and knee. This will involve an Anesthetist giving an injection into the nerve, which lies in the upper part of the leg. The other group will receive an injection that contains pain relieving drugs into the joint itself at the time of surgery. This will be done by the surgeon. All participants will be asked to report their pain scores at various intervals, so that these can be recorded. Other information which will be documented will include:
The amount of the pain relieving medication used after the operation.
The time it takes to work through physiotherapy goals.
The time it takes to recover in hospital after the operation.

What are the possible benefits and risks of participating?
We cannot promise that patients will gain any immediate benefit from taking part in the research. However, the information gathered will help improve the care of patients who have knee replacements in the future. There are no major risks associated with this research study. The risks of having knee replacement surgery will have been discussed with you by the surgeon.

Where is the study run from?
Lancashire Teaching Hospital (UK)

When is the study starting and how long is it expected to run for?
May 2012 to July 2012

Who is funding the study?
Lancashire Teaching Hospitals NHS Foundation Trust (UK)

Who is the main contact?
Mr George McLauchlan
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Post operative pain relief following knee arthroplasty - an exploratory study comparing the efficacy of a single shot femoral nerve block against intra-articular analgesic injection

Study objectives
The two methods of pain relief being compared are femoral nerve blocks, which cause numbing of the thigh and knee, versus the use of injections which contain drugs used for pain relief into the knee joint.

To measure which method is more effective, we will be measuring the following:
1. The pain scores of patients
2. The amount of patient-controlled pain relief used
3. The time taken to achieve physiotherapy goals.
4. The length of stay in hospital

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee Northwest Preston, 15/03/2012, ref: 12/NW/0153

Study design
Randomised control trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Knee arthroplasty

Interventions
Randomised control trial looking at single shot femoral nerve blocks versus Intra articular injections. The data will be analysed using stats direct and MS Excel.

Prior to surgery, patients will be randomly allocated to either group A or group B. Group A will receive a one shot femoral nerve block containing 30ml or 0.2% ropivacaine post surgery.

Group B will receive a single intra articular knee injection containing 200ml 0.2% ropivacaine, 1ml 1:1000 adrenaline and 30mg ketolorac.

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome(s)
Pain scores in the two patient groups, recorded 4 hours post operatively, before and after physiotherapy

Key secondary outcome(s))
1. The amount of patient-controlled pain relief used
2. The time taken to achieve physiotherapy goals
3. The length of stay in hospital

Completion date
15/07/2012

Eligibility

Key inclusion criteria

Patients having a total knee arthroplasty between the dates of May 2012- July 2012 who have capacity to consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Any patients that lack capacity to consent to the study
2. Patients who are unwilling to consent.
3. Patients who may be acutely confused or suffer from dementia
4. Patients who have a known allergy, intolerance or previous reaction to any of the drugs being administered

Date of first enrolment
15/05/2012

Date of final enrolment
15/07/2012

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Lancashire Teaching Hospitals NHS Foundation Trust
Preston
United Kingdom
PR2 9HT

Sponsor information

Organisation
Lancashire Teaching Hospitals NHS Foundation Trust (UK)

ROR
https://ror.org/02j7n9748

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Lancashire Teaching Hospitals NHS Foundation Trust (UK)

Results and Publications

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?
Results article	results	01/10/2013		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes