

Can local anaesthetic injection reduce pain in knee arthroplasty?

Submission date 12/09/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 03/01/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 28/03/2018	Condition category Signs and Symptoms	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

In the UK many people with painful arthritis undergo a total knee replacement operation every year. Despite the best efforts of doctors and nursing staff, many patients are still in some pain during the first 24 hours after the operation. Some evidence has shown that the injection of some local anaesthetic medication around the knee replacement during the operation may reduce pain following the surgery.

We do not know if this technique definitely works and we aim to see if injection of local anaesthetic medicine around the knee replacement during the operation does reduce the pain patients have after the surgery.

Who can participate?

We need about 44 patients to participate for us to know if the injection works or not. We hope patients who are waiting for a total knee replacement at our hospital will agree to take part. Both men and women over the age of eighteen could participate.

We would not include patients who suffer from chronic pain syndromes requiring them to take morphine patches or gabapentin (a medicine that works on nerve pain).

What does the study involve?

When it is decided that you want to have a knee replacement, we will give you a leaflet about the study. Before the operation all patients are seen in a pre-operation clinic. At this time we will talk in more detail about the study, and ask you to sign a consent form if you wish to take part. If you agree to take part, you will be randomly allocated to one of two groups. Both groups will receive exactly the same medicines for pain that all our patients currently get following knee surgery. As well as these medicines, one group will receive an injection of anaesthetic around the knee during the surgery. The other group will receive an injection of saline (salt water). After the operation all patients receive morphine from a pump which they control themselves. We will not leave you in pain. After the operation we will record how much morphine you need to be comfortable, and ask you to rate your pain from 0 to 10. We will compare the amount of morphine people used in each group and their pain scores. This will tell us if the injection does make people more comfortable after the operation.

What are the possible benefits and risks of participating?

If you are in the group that has the anaesthetic injection you may be more comfortable, although this is not certain. If this study shows the injection does make people more comfortable after the operation you may benefit from it in the future if you have further knee surgery.

The local anaesthetic medicine we are using has been used for a long time both in this country and abroad. Side effects are extremely rare. In very rare cases the medicine can act on the heart, changing how it beats. This has not happened in any of the studies using this technique. We monitor the heart rate of all patients during the operation, so if this did happen we would know and be able to treat it.

Where is the study run from?

The study will take place at the Leicester General Hospital.

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

We hope to start the study in November 2011. It will take about 6 months.

Who is funding the study?

Overall the University Hospitals of Leicester (UK), although it has to be noted that the medicines we are using are available in the hospital, the doctors performing the study will perform it alongside their normal duties and as such the study should not cost anything to perform.

Who is the main contact?

Mr David Gibbs, Specialty Registrar in Trauma and Orthopaedic surgery, Leicester General Hospital.

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Contact information

Type(s)

Scientific

Contact name

Mr David Gibbs

Contact details

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Additional identifiers

Protocol serial number

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Study information

Scientific Title

A randomised controlled trial investigating the efficacy of local anaesthetic infiltration during total knee replacement surgery at reducing post operative pain

Study objectives

The injection of local anaesthetic during total knee replacement surgery reduces patient pain and discomfort following the operation

Ethics approval required

Old ethics approval format

Ethics approval(s)

University Hospital Leicester NHS Trust Clinical Ethics Committee

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Pain following knee arthroplasty

Interventions

Patients undergoing knee arthroplasty will be randomly allocated to receive local infiltration analgesia or saline. Pain following surgery will be measured.

150ml of 0.1% levobupivacaine + 1:200 000 adrenaline will be infiltrated by the surgeon during surgery as follows: 50ml into posterior capsule prior to placement of implant, 50ml into synovium and peritendinous areas and 50ml into subcutaneous tissues whilst cement is setting.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Pain at rest measured using the visual analogue scale.

Key secondary outcome(s)

1. Quantity of opiate medication required
2. Length of hospital stay
3. Pain during exercise measured using the visual analogue scale

Completion date

24/05/2012

Eligibility

Key inclusion criteria

1. Undergoing total knee replacement surgery under spinal anaesthesia at Leicester General Hospital
2. Ability to give informed consent to their involvement in the trial
3. Male and female participants
4. Aged 18 - 100

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Pre-existing chronic pain
2. Use of regular strong opiate medication prior to surgery; specifically, patients using opiate patches or Gabapentin

Date of first enrolment

24/10/2011

Date of final enrolment

24/05/2012

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Leicester General Hospital

Leicester

United Kingdom

LE5 4PW

Sponsor information

Organisation

University Hospitals of Leicester (UK)

ROR

<https://ror.org/02fha3693>

Funder(s)

Funder type

University/education

Funder Name

University Hospitals of Leicester (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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes