

# Can local anaesthetic injection reduce pain in knee arthroplasty?

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<b>Registration date</b> 03/01/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 28/03/2018	<b>Condition category</b> 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.

david.gibbs@uhl-tr.nhs.uk

## Contact information

### Type(s)

Scientific

### Contact name

Mr David Gibbs

### Contact details

Leicester General Hospital  
Department of Orthopaedic Surgery  
Gwendolen Road  
Leicester  
United Kingdom  
LE5 4PW

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

## Secondary identifying numbers

1

# 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

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

Not available in web format, please contact Mr Timothy Green ([timothy.green@uhl-tr.nhs.uk](mailto:timothy.green@uhl-tr.nhs.uk)) to request a patient information sheet

## 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 measure**

Pain at rest measured using the visual analogue scale.

**Secondary outcome measures**

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

**Overall study start date**

24/10/2011

**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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

44

**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**

England

United Kingdom

**Study participating centre**

**Leicester General Hospital**

Leicester

United Kingdom

LE5 4PW

**Sponsor information****Organisation**

University Hospitals of Leicester (UK)

**Sponsor details**

c/o Mr Timothy Green

University Hospitals of Leicester

Gwendolen Road

Leicester

Leicester

England

United Kingdom

LE5 4PW

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.uhl-tr.nhs.uk/>

**ROR**

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

**Funder(s)**

**Funder type**

University/education

**Funder Name**

University Hospitals of Leicester (UK)

## **Results and Publications**

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Not provided at time of registration