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Can local anaesthetic injection reduce pain in knee arthroplasty?

Submission date
12/09/2011

Recruitment status
No longer recruiting

Registration date
03/01/2012

Overall study status
Completed

Last Edited
28/03/2018

Condition category
Signs and Symptoms

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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
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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) 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 peritendonous areas and 50ml into subcutanous 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
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Leicester
England
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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