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Comparison of local anaesthetic nerve blocks that still allow a patient to walk versus standard injection of local anaesthetic, for pain relief after knee joint replacement surgery

Submission date
17/12/2015

Recruitment status
Stopped

Registration date
14/01/2016

Overall study status
Stopped

Last Edited
06/07/2017

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
Effective pain relief is very important for recovery and rehabilitation after a knee replacement operation. Ideally, pain relief would allow a patient to move their leg and be able to stand or walk (mobilise) straight away after an operation, without complications. Pain relief is often provided using painkiller tablets, however there is also the option of numbing the painful area by injecting a local anaesthetic around the nerves in the area of pain (nerve block). A new nerve block technique has recently by been developed, called the motor sparing knee (MSK) block. This aims to temporarily “numb” the nerves carrying pain signals from the knee, but leave the nerves to the muscles unaffected so a patient can move their leg straight away after a knee replacement operation without much pain. This therefore could have the potential to provide not just better pain relief, but helps with effective physiotherapy after an operation. In this research project this technique will be compared with the established practice of injecting large volumes of local anaesthetics around the knee joint. The aim of this study is to compare the pain relieving effects of MSK block and traditional nerve block following knee replacement surgery.

Who can participate?
Adults undergoing knee replacement surgery.

What does the study involve?
Participants are randomly allocated to one of two groups, who both undergo the knee replacement operation under general anaesthetic. For participants in the first group, the surgeon injects the local anaesthetic (chirocaine) into the knee joint in order to provide post-operative pain relief. For participants in the second group, guided using an ultrasound machine for precision, 15ml of 0.5% chirocaine is injected into several specific nerves in the thigh in order to provide post-operative pain relief (MSK block). In the 48 hours following their surgery, participants in both groups are visited by specialist pain nurses who ask them to rate their pain levels. Participants also see a physiotherapist 4 hours after surgery, and then again 1 and 2 days after surgery, in order to measure how long it takes them to mobilise.

What are the possible benefits and risks of participating?
Participants could benefit from lower pain levels, the ability to move their knee and walk sooner, a faster discharge from hospital and being able to return to normal activities in daily life sooner. Al;so, as the MSK block procedure is ultrasound-guided, there is a lower risk of nerve injury. Risks of taking part in this study are low however there is a remote risk of a first time allergy to the anaesthetic used.

Where is the study run from?
Morriston Hospital, Swansea (UK)

When is the study starting and how long is it expected to run for?
January 2015 to December 2018

Who is funding the study?
Welsh Pain Society (UK)

Who is the main contact?
Dr John Dingley

Contact information

Type(s)
Scientific

Contact name
Dr John Dingley

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Additional identifiers

EudraCT/CTIS number

IRAS number
151413

ClinicalTrials.gov number

Secondary identifying numbers
IRAS ID No: 151413

Study information

Scientific Title

Comparison of motor sparing knee (MSK) blocks versus local infiltration in primary total knee replacement (TKR)

Acronym
MSK study

Study objectives
Primary objective:
To compare average Numerical Pain Scores over the first 24 hours between the MSK and Local Anaesthetic Infiltration (LAI) groups. We hypothesise that there will be a lower pain score in the MSK group and decreased use of analgesic drugs post-operatively.

Secondary Objectives:
1. To compare opioid usage between the two groups. We hypothesise there will be a reduction in opioid usage in the first 48 hours between the MSK and LAI groups.
2. Time to mobilisation will be reviewed. We hypothesise there will be no delay in time to mobilise between the two groups.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Wales REC 6 Research Ethics Committee, 27/10/2015

Study design
Single-centre double-blind 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 use the contact details below to request a patient information sheet.

Health condition(s) or problem(s) studied
Pain after knee joint replacement surgery

Interventions
Participants are randomly allocated to one of two groups.

Group 1: Participants will receive a standard general anaesthetic with standard monitoring. In addition, the joint will be infiltrated with the local anaesthetic chirocaine by the surgeon to provide a degree of post-operative pain relief (the standard technique).

Group 2: Participants will receive the same general anaesthesia as Group A as well as receiving an MSK block. This involves injecting a total of 15mls of 0.5% chirocaine into the lateral cutaneous nerve of the thigh (LCNT) running between sartorius and tensor fascia lata, the intermediate cutaneous nerve of thigh (IMCNT) traversing the sartorius muscle just below the femoral triangle and the infra-patellar nerve (IPN) in the subsartorial canal at mid-thigh level. The genicular branches identified deep to vastus lateralis and medialis at the femoral epicondyles and the inferior genicular branch located medial to the tibial plateau will be blocked using 5mls of 0.5% chirocaine each. The posterior capsule is blocked by placing 5mls of 0.5% chirocaine on the deep aspect of the popliteal artery at the level of the knee distal to the sciatic nerve bifurcation.

Post-operatively, pain is assessed using the numeric rating scale (NRS) in all participants. If the pain is recorded as 4 or greater, intravenous morphine is to be titrated at 2mg aliquots until the pain is controlled to a score of 2 or less. If there is a high opioid requirement in recovery (16mg or more) then the anaesthetist will review the patient to assess whether morphine patient controlled analgesia (PCA) is required. Pain will be measured 4 times a day for 48 hours following surgery.

As part of the standard enhanced recovery programme the patient is mobilised on the same day of surgery, preferably after four hours (providing vital signs are stable). Physiotherapists will ensure that patients have adequate motor function prior to mobilisation. Standard physiotherapy assessment charts with some modifications will be utilised to obtain a record of distance walked with aid, ability to hold quadriceps tension/lift leg, range of motion and highest pain score during physiotherapy. This will be repeated by the physiotherapist on postoperative days 1 and 2.

Intervention Type
Other

Primary outcome measure
Pain will be measured using the Numerical Rating Score of pain over a 48 hour period after surgery collected at 8am, 12pm, 5pm and 10pm on each day.

Secondary outcome measures
1. Opioid use over the first 48 hours after surgery is recorded by blind assessors throughout each patient's hospital stay
2. Time to mobilisation after surgery will be determined by recording walking distance, ability to complete leg lifts and range of motion during physiotherapy 4 hours post-surgery, 1 and 2 days post-surgery

Overall study start date
01/09/2014

Completion date
30/06/2016

Reason abandoned (if study stopped)

Objectives no longer viable

Eligibility

Key inclusion criteria
1. Primary knee replacement
2. Aged between 18 to 80 years
3. Able to give valid consent
4. No history of chronic pain unrelated to knee pain
5. No history of extensive trauma to the joint

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
24

Key exclusion criteria
1. Lack of capacity for consent
2. Neuropathic pain / sensory disorders in leg to be operated on
3. Diabetes Mellitus
4. Previous major bone surgery in the knee to be operated on
5. Intolerance to study drugs
6. Local infection at site of operation
7. Significant GORD
8. BMI greater than 30
9. ASA 4/5
10. Long term opioid usage

Date of first enrolment
01/01/2016

Date of final enrolment
30/06/2016

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Morriston Hospital
Anaesthetic Department
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SA6 6NL

Sponsor information

Organisation
Abertawe Bro Morgannwg University Trust

Sponsor details
Morriston Hospital
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Sponsor type
Hospital/treatment centre

Website
http://www.wales.nhs.uk/sitesplus/863/home

ROR
https://ror.org/04zet5t12

Funder(s)

Funder type
Other

Funder Name
Welsh Pain Society

Results and Publications

Publication and dissemination plan
Dissemination of results as presentations/abstracts at local meetings e.g. Welsh Pain Society and Regional meetings such as the British Pain Society, October 2016 onwards. Subsequent publication in peer reviewed scientific journal is also planned.

Intention to publish date
31/01/2017

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date