ISRCTN24271997 https://doi.org/10.1186/ISRCTN24271997

A comparison of the need for opiate pain relief medication after elective hip replacement surgery between patients given Local Anaesthetic Infiltration to the new joint and then an infusion of either local anaesthetic or placebo around the new joint

Submission date
07/08/2011

Recruitment status
No longer recruiting

Registration date
17/01/2012

Overall study status
Completed

Last Edited
10/05/2018

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Hip replacements (hip arthroplasty) are associated with high levels of pain after the operation. Many anaesthetic techniques have been tested in an attempt to reduce this problem. However, the need for opiate analgesia (pain relief) after the operation remains high. This is associated with the potential for multiple side effects such as nausea, constipation and drowsiness. The use of continuous wound infiltration with local anaesthetic has been investigated with some success. However, more opiate was required when mobilisation commenced. In addition to wound infiltration, a method of intra-articular infusion (joint injection) may reduce the need for opiate medication when the joint is mobilised. The aim of this study is to find out whether a pain pump delivering continuous intra-articular infusion of local anaesthetic provides pain relief and improves mobility in patients following hip replacement.

Who can participate?
Patients attending for elective primary hip arthroplasty at Chapel Allerton Hospital.

What does the study involve?
Participants are randomly allocated to one of two groups. One group are treated with a pain pump that delivers a continuous intra-articular infusion of local anaesthetic following hip replacement. The other group receive an infusion of placebo (salt solution) via the same pump. All patients receive an infiltration of local anaesthetic into the joint at the end of surgery and also receive the current standard anaesthetic technique for hip replacement surgery.

What are the possible benefits and risks of participating?
Benefits include potentially better pain control and reduced need for opiates and therefore

fewer side effects, earlier mobilisation, earlier hospital discharge and reduced rate of medical complications. If the study changes future practice for the better, the patient will benefit if undergoing further joint replacements. Any positive outcomes from this study will impact on a large number of patients. The drugs and doses to be used in this study have been used frequently in other studies and there are no reports of serious side effects.

Where is the study run from?
Chapel Allerton Hospital (UK)

When is the study starting and how long is it expected to run for?
October 2011 to October 2013

Who is funding the study?
The Leeds General Infirmary Challenge Fund (UK)

Who is the main contact?
Mr Martin Stone

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
RR11/ 9781

Study information

Scientific Title
The efficacy of continuous intra-articular infusion of local anaesthetic agent following elective primary hip arthroplasty: a single-centre double-blinded randomised controlled trial

Acronym
LIA

Study objectives
1. To determine whether the use of a continuous intra-articular infusion of local anaesthetic reduces the need for post operative opiate use in patients undergoing hip replacement
2. To determine:
2.1. Whether patients receiving continuous infusion of local anaesthetic mobilise earlier than those in the control group
2.2. Whether patients receiving continuous infusion of local anaesthetic are more comfortable when they mobilise compared to controls
3. To compare time to discharge in the two groups
4. To compare the rate of side effects/complications lower in the two groups

Ethics approval required
Old ethics approval format

Ethics approval(s)
West Leeds Research Ethics Committee, September 2011

Study design
Single-centre double-blinded 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
Primary hip arthroplasty

Interventions
The total duration of treatment is 48 hours from the time of surgery and the total duration of time in the study is for 6-12 weeks from time of discharge.

1. Attendance at pre-assessment clinic (no additional visit to a patient not in the study), study information given to potential trial participants.
2. Admission to orthopaedic unit and written consent obtained
3. Administration of standard anaesthetic technique (spinal +/- sedation or light general

anaesthetic) as for non-trial patients
4. Standard hip replacement performed as for non-trial patients
5. Study intervention performed; local anaesthetic mixture infiltration (ropivacaine 300mg, ketorolac 30mg and adrenaline 0.5mg) and insertion of pain pump device
6. Treatment group receive a 48h infusion of 0.25% bupivicaine via the pain pump device into the tissues surrounding the new joint. Placebo group receive an infusion over 48h of 0.9% saline in the same way.
7. Patient care in recovery area as for non-trial patients
8. Assessment of pain using standardised pain scoring technique
9. Physiotherapy session and routine observations and ward care including analgesia and antiemetics if needed as for non-trial patients
10. Routine blood test on morning after surgery as for non-trial patients
11. Removal of pain pump device at 48h
12. Routine follow up clinic appointment as for non-trial patients

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Adrenaline, bupivicaine, ketorolac, ropivacaine

Primary outcome measure
A 30% reduction in the number of patients requiring opiate analgesia in the 48 hours post-operative period in the treatment group compared to the placebo group.
1. Pain is measured using a 10-point Visual Analogue Score (VAS)
2. The case report file for each study participant includes data collection on pain scores, opiate and other analgesia requirements and anti-emetic use.

Secondary outcome measures
1. Pain scores postoperatively as measured using a 100mm Visual Analogue Score (VAS)
2. Time to first mobilisation in hours
3. Time to independent mobilisation in hours
4. Time to fulfill discharge criteria in days
5. Time to hospital discharge in days
6. Urinary retention post operatively indicated by requirement for urinary catheter
7. Deep vein thrombosis (DVT) / pulmonary embolism (PE) rate at up to outpatient follow up (6-12 weeks post operation)
8. Side effects and general medical complications

Overall study start date
01/10/2011

Completion date
01/10/2013

Eligibility

Key inclusion criteria

1. All patients fit to undergo elective primary hip replacement at Chapel Allerton Hospital
2. Patients who are able to give informed consent
3. American Society of Anesthesiologists (ASA) 1-3

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
70, 35 randomised to either the treatment or placebo groups

Key exclusion criteria
1. Any patient already taking opioid analgesics or non-steroidal anti-inflammatory drugs (NSAID)
2. Allergy/sensitivity to local anaesthetics agents
3. Allergy/sensitivity to NSAIDs
4. Allergy/sensitivity to adrenaline
5. Patients taking anti-coagulant medication
6. Severe liver disease
7. Severely impaired renal function
8. Severe heart failure
9. Active cerebrovascular bleeding
10. Severe coagulation disorders
11. Severe asthma or previous bronchospasm with NSAIDs
12. Porphyria
13. Active peptic ulcer disease or acute gastrointestinal (GI) bleed
14. Any patient unable to consent or understand the pump function
15. Bilateral hip replacements
16. Pregnancy/lactation
17. Patients already enrolled in another study

Date of first enrolment
01/10/2011

Date of final enrolment
01/10/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Chapel Allerton Hospital
Leeds
United Kingdom
LS7 4SA

Sponsor information

Organisation
Leeds Teaching Hospitals NHS Trust (UK)

Sponsor details
c/o Mr Neville Young
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Sponsor type
Hospital/treatment centre

Website
http://www.leedsteachinghospitals.com/

ROR
https://ror.org/00v4dac24

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Leeds General Infirmary - Challenge Fund (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