# 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

<b>Submission date</b> 07/08/2011	<b>Recruitment status</b> No longer recruiting	<ul><li>Prospectively registered</li></ul>
		☐ Protocol
Registration date	Overall study status	Statistical analysis plan
17/01/2012	Completed	Results
Last Edited	Condition category	Individual participant data
10/05/2018	Musculoskeletal Diseases	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

Mr Martin Stone

#### Contact details

Chapel Allerton Hospital Orthopaedic Department Chapeltown Road Leeds United Kingdom LS7 4SA

# Additional identifiers

Protocol serial number 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

## Study type(s)

Treatment

# 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(s)

A 30% reduction in the number of patients requiring opiate analgesia in the 48 hours postoperative 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.

## Key secondary outcome(s))

- 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

# 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

# Healthy volunteers allowed

No

# Age group

Adult

#### Sex

Αll

# 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

United Kingdom

England

# Study participating centre Chapel Allerton Hospital

Leeds United Kingdom LS7 4SA

# Sponsor information

## Organisation

Leeds Teaching Hospitals NHS Trust (UK)

## **ROR**

https://ror.org/00v4dac24

# Funder(s)

## Funder type

Hospital/treatment centre

## Funder Name

Leeds General Infirmary - Challenge Fund (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 11/11/2025 No Yes

Participant information sheet