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Investigation into the effects of steroid and local anaesthetic infiltration into soft tissues in total hip replacement wounds on post-operative pain relief

Submission date
28/09/2007

Recruitment status
No longer recruiting

Registration date
28/09/2007

Overall study status
Completed

Last Edited
24/10/2016

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
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2006-001580-30

Protocol serial number
N0202183594

Study information

Scientific Title
Investigation into the effects of steroid and local anaesthetic infiltration into soft tissues in total hip replacement wounds on post-operative pain relief

Study objectives
1. What are the effects on pain relief after total hip replacement of injecting steroid and local anaesthetic into hip wounds at operation?
2. Does the above have an effect on amount of morphine required postoperatively, the time taken to walk after operation, the total time spent in hospital and the rate of infection?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Prospective, randomised, double blind trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Signs and Symptoms: Pain

Interventions
The study will be a prospective, randomised, double blind trial comparing outcomes of three treatment groups:
1. Local anaesthetic only
2. Local anaesthetic and steroid
3. Placebo

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
steroid and local anaesthetic

Primary outcome(s)
Volume of morphine administered by PCA post op.

Key secondary outcome(s))

1. Visual analogue pain scores
2. Time to first dose of morphine
3. Time to mobilisation
4. Time to discharge
5. Complications ie delayed wound healing, dehiscence

Completion date
31/10/2006

Eligibility

Key inclusion criteria
Patients undergoing primary total hip replacement surgery for osteoarthritis will be selected for the trial from the waiting lists of two orthopaedic surgeons using the same prostheses.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

Key exclusion criteria
1. Patients who are on regular steroid treatment
2. Those taking strong opioid analgesia regularly
3. Patients who are diabetic
4. In addition, patients with a history of peptic ulcer disease will be excluded as steroid treatment is contraindicated with this condition

Date of first enrolment
03/08/2006

Date of final enrolment
31/10/2006

Locations

Countries of recruitment
United Kingdom

England

Study participating centre

Royal Cornwall Hospitals NHS Trust
Truro
United Kingdom
TR1 3LJ

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Funder(s)

Funder type
Government

Funder Name
Royal Cornwall Hospitals NHS Trust

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration