ISRCTN60588943 https://doi.org/10.1186/ISRCTN60588943

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	[_] Prospectively registered [_] Protocol
Registration date 28/09/2007	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 24/10/2016	**Condition category** Signs and Symptoms	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr Darren Fern

Contact details
Royal Cornwall Hospitals NHS Trust
Treliske
Truro
United Kingdom
TR1 3LJ
+44 (0)1872 253434
Darren.Fern@rcht.cornwall.nhs.uk

Additional identifiers

EudraCT/CTIS number
2006-001580-30

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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 measure
Volume of morphine administered by PCA post op.

Secondary outcome measures
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

Overall study start date
03/08/2006

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

Age group
Not Specified

Sex
Not Specified

Target number of participants
Not provided at time of registration

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
England

United Kingdom

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

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Not defined

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Royal Cornwall Hospitals NHS Trust

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