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Does a pain pump provide increased analgesia in forefoot reconstruction surgery?

Submission date 29/09/2006	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 29/09/2006	**Overall study status** Stopped	
Last Edited 21/07/2010	**Condition category** Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0051166093

Study information

Scientific Title

Study objectives
Is a Patient Controlled Regional Anaesthesia (PCRA) technique better for patients undergoing forefoot reconstruction than the standard technique of nerve blocks and oral medication?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Surgery: Forefoot reconstruction

Interventions
Patients will be randomised into either the pain pump group or the standard technique group. All will receive a standardised general anaesthetic. Post operatively, visual analogue pain scores and patient satisfaction will be recorded. The patients will be discharged with the pump in situ.

Added 20/07/10: the trial never started.

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure
Visual Analogue pain scores. Patient satisfaction levels.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/05/2005

Completion date
01/05/2006

Reason abandoned (if study stopped)
Lack of staff/facilities/resources

Eligibility

Key inclusion criteria
30 patients undergoing forefoot reconstruction.

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
30

Key exclusion criteria
1. Allergy to local anaesthetic
2. Any patient with previous surgery to that foot
3. Any patient requiring more extensive surgery e.g. Weil's osteonomies
4. Allergies/intolerances to NSAIDs

Date of first enrolment
01/05/2005

Date of final enrolment
01/05/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Brighton & Sussex University Hospitals NHS Trust (PR)
Haywards Heath
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Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
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Sponsor type
Government

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

Funder(s)

Funder type
Government

Funder Name
Brighton and Sussex University Hospitals NHS Trust (UK) NHS R&D Support Funding

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