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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

Contact name
Mr Philip Stott

Contact details
Brighton & Sussex University Hospitals NHS Trust (PR)
Princess Royal
Lewes Road
Haywards Heath
United Kingdom
RH16 4EX
philstott@hotmail.com

Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

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(s)
Visual Analogue pain scores. Patient satisfaction levels.

Key secondary outcome(s)
Not provided at time of registration

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

Healthy volunteers allowed
No

Age group
Adult

Sex
Not Specified

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
United Kingdom

England

Study participating centre
Brighton & Sussex University Hospitals NHS Trust (PR)
Haywards Heath
United Kingdom
RH16 4EX

Sponsor information

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

Funder(s)

Funder type
Government

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

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration