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A Randomised, Prospective, Double Blinded, Placebo Controlled Trial to Determine the Efficacy of Continuous Infusion Ankle Block Compared to Standard Single Bolus Block in the Management of Postoperative Pain Following Foot and Ankle Surgery

Submission date 29/09/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 29/09/2006	**Overall study status** Completed	
Last Edited 11/10/2011	**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
N0360177161

Study information

Scientific Title

Study objectives
To assess the effectiveness of a single administration (bolus) of local anaesthetic to the nerves that supply the foot and ankle versus a bolus and continuous infusion of local anaesthetic to the same nerves in order to manage post operative pain following foot and ankle surgery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised prospective double blinded placebo 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: Foot and ankle

Interventions
Continuous infusion ankle block vs standard single bolus block.

Intention to treat analysis will be used. The outcomes of the two treatment groups will be evaluated using two-sample t tests, with 95% confidence intervals reported for the difference in means. Secondary binary outcomes will also be analysed using two sample t tests, but using a significance level of 1%. All analyses will be adjusted (using linear regression) for confounding

variables that may differ by chance between the treatment groups. Stata for Windows (StataCorp, USA) will be the statistical package of choice.

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure
Mean patient visual analogue pain scores over 72 hours post-operatively.

Secondary outcome measures
1. Time to mobilise
2. Time to discharge

Overall study start date
01/06/2006

Completion date
01/06/2007

Eligibility

Key inclusion criteria
Patients undergoing ankle and hindfoot surgery.

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
56

Key exclusion criteria
1. Dementia
2. Peripheral neuropathy

Date of first enrolment
01/06/2006

Date of final enrolment
01/06/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
North Hampshire Hospital NHS Trust
Basingstoke
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RG24 9NA

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
North Hampshire Hospitals NHS Trust (UK)

Funder Name
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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2010		Yes	No