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

Plain English summary of protocolNot provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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 United Kingdom 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 London United Kingdom SW1A 2NL +44 (0)20 7307 2622 dhmail@doh.gsi.org.uk

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