

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
Registration date 29/09/2006	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 11/10/2011	Condition category Surgery	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Primary study design

Interventional

Study design

Randomised prospective double blinded placebo controlled trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

1. Time to mobilise
2. Time to discharge

Completion date

01/06/2007

Eligibility

Key inclusion criteria

Patients undergoing ankle and hindfoot surgery.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Not Specified

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

United Kingdom

England

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

Funder(s)

Funder type

Government

Funder Name

North Hampshire Hospitals NHS Trust (UK)

Funder Name

NHS R&D Support Funding

Results and Publications

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