# 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	<ul><li>Prospectively registered</li></ul>		
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 protocol

Not provided at time of registration

# Contact information

**Type(s)**Scientific

## Contact name

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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

## Study design

Randomised prospective double blinded placebo controlled trial

## Primary study design

Interventional

## 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