

# A randomised, placebo controlled trial of levobupivacaine or the combination of levobupivacaine and clonidine when administered as a sciatic perineural infusion for the prevention of phantom limb pain after lower limb amputation

<b>Submission date</b> 13/10/2006	<b>Recruitment status</b> Stopped	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 18/04/2007	<b>Overall study status</b> Stopped	<input type="checkbox"/> Protocol
<b>Last Edited</b> 28/03/2013	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

**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**

06/S1402/98

## **Study information**

**Scientific Title**

### **Study objectives**

The objective of the proposed study is to investigate the incidence of phantom limb pain of patients after lower limb amputation when given a seven day sciatic perineural infusion of saline, levobupivacaine 1.25 mg/ml or the combination of levobupivacaine 1.25 mg/ml and clonidine 1 mg/ml.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

No ethics approval as of 13/10/2006.

### **Study design**

A randomised, double blind placebo controlled trial.

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Not specified

### **Study type(s)**

Prevention

### **Participant information sheet**

### **Health condition(s) or problem(s) studied**

Phantom limb pain in amputation cases

### **Interventions**

Trial status changed to 'stopped' as of 28/03/2013 as it never started.

Patients will be randomised to one of three groups of a seven day sciatic perineural infusion of:

Group A: Perineural saline

Group B: Perineural levobupivacaine 1.25 mg/ml

Group C: Perineural levobupivacaine 1.25 mg/ml and clonidine 1 mg/ml

## **Intervention Type**

Drug

## **Phase**

Not Specified

## **Drug/device/biological/vaccine name(s)**

Levobupivacaine and clonidine

## **Primary outcome measure**

Incidence of phantom limb pain

## **Secondary outcome measures**

1. To assess the incidence of stump pain and phantom limb sensation
2. To assess the degree of postoperative pain relief
3. To compare the need for rescue analgesia
4. To measure the side effect profile of both groups
5. To measure functional outcomes such as time to first drinking, eating, mobilisation and micturition
6. To measure time to readiness for discharge and length of hospital stay
7. Quality of life scores such as Short Form health survey (SF 36), Client Satisfaction Questionnaire (CSQ), Global Self Esteem questionnaire (GSE), Hospital Anxiety Depression Scale, Amputation Activity Score, Neuropathic Pain Score, measured at one, three, six and 12 months

## **Overall study start date**

01/03/2007

## **Completion date**

01/03/2011

## **Reason abandoned (if study stopped)**

Lack of funding/sponsorship

# **Eligibility**

## **Key inclusion criteria**

All patients presenting for elective lower limb amputation will be approached for recruitment to this study.

## **Participant type(s)**

Patient

## **Age group**

Not Specified

**Sex**

Not Specified

**Target number of participants**

180

**Key exclusion criteria**

1. Signs of cardiac failure (third heart sound, lung crepitations)
2. Presence of seizures, dementia, or encephalopathy
3. Patients with any terminal illness with a life expectancy less than three months

**Date of first enrolment**

01/03/2007

**Date of final enrolment**

01/03/2011

**Locations****Countries of recruitment**

Scotland

United Kingdom

**Study participating centre**

University Department of Anaesthesia

Dundee

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**Sponsor information****Organisation**

NHS Tayside (UK)

**Sponsor details**

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**Sponsor type**

Government

**Website**

<http://www.nhstayside.scot.nhs.uk/>

**ROR**

<https://ror.org/000ywep40>

**Funder(s)****Funder type**

Not defined

**Funder Name**

Not provided at time of registration.

**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