

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

Submission date 13/10/2006	Recruitment status Stopped	☐ Prospectively registered
Registration date 18/04/2007	Overall study status Stopped	☐ Protocol
Last Edited 28/03/2013	Condition category Nervous System Diseases	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☐ 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

Protocol serial number

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

Study type(s)

Prevention

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(s)

Incidence of phantom limb pain

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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**

United Kingdom

Scotland

Study participating centre

University Department of Anaesthesia

Dundee

United Kingdom

DD1 9SY

Sponsor information

Organisation

NHS Tayside (UK)

ROR

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

Funder(s)

Funder type

Not defined

Funder Name

Not provided at time of registration.

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration