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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

Registration date
18/04/2007

Last Edited
28/03/2013

Recruitment status
Stopped

Overall study status
Stopped

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] 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

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
United Kingdom
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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