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Randomised prospective study comparing epidural analgesia perioperatively and 24 hours preoperatively for the prevention of postoperative stump pain and phantom limb pain following major amputation

Submission date 30/09/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 30/09/2004	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 28/11/2014	**Condition category** Surgery	[_] 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
N0185139350

Study information

Scientific Title
Randomised prospective study comparing epidural analgesia perioperatively and 24 hours preoperatively for the prevention of postoperative stump pain and phantom limb pain following major amputation

Study objectives
Does commencing an epidural 24 hours prior to limb amputation reduce post-operative and phantom limb pain compared with commencing it at the time of the operation?

Aims and Objectives: To demonstrate whether there is a reduction in phantom limb and post operative stump pain as a result of lower limb amputation, when epidural analgesia is commenced 24 hours prior to surgery rather than at the time of surgery.

Study endpoints: To set a precedent for commencing epidural infusion 24 hours before lower limb amputation as the best method of preventing stump and phantom limb pain.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Surgery: Amputation

Interventions

Study group to be selected from patients scheduled for lower limb amputation who are randomised into two groups:
1. To commence epidural at time of surgery
2. To commence epidural 24hr prior to surgery

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure
Pain scores to be assessed:
1. Immediately post-operatively. Subjective and objective scoring using a visual analogue score, and a record of morphine requirements for post-operative pain.
2. Phantom limb pain; assessed as present or absent at 3, 6 and 12 month follow up.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/07/2003

Completion date
01/02/2005

Eligibility

Key inclusion criteria
1. Patients above the age of 18
2. All patients undergoing scheduled lower limb amputation will be considered

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Non general anaesthetic (GA)
2. Emergency surgery

3. Unable to give consent
4. Contraindications to epidural
5. Anticoagulated

Date of first enrolment
01/07/2003

Date of final enrolment
01/02/2005

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Derriford Hospital
Plymouth
United Kingdom
PL6 8DX

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Plymouth Hospitals NHS Trust (UK)

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