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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

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| **Submission date**<br>30/09/2004 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol |
| **Registration date**<br>30/09/2004 | **Overall study status**<br>Completed | [_] Statistical analysis plan<br>[_] Results |
| **Last Edited**<br>28/11/2014 | **Condition category**<br>Surgery | [_] Individual participant data<br>[_] Record updated in last year |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

**Contact name**
Mr T Edwards

**Contact details**
C/O Cdr Lambert's Secretary
Department of General Surgery
Derriford Hospital
Derriford
Plymouth
United Kingdom
PL6 8DX

## 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