

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 30/09/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 28/11/2014	Condition category Surgery	<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

Protocol serial number
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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

United Kingdom

England

Study participating centre

Derriford Hospital

Plymouth

United Kingdom

PL6 8DX

Sponsor information

Organisation

Department of Health

Funder(s)

Funder type

Government

Funder Name

Plymouth Hospitals NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration