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# A randomised controlled study of Epidural Fentanyl Analgesia following Lumbar Laminectomy

| Submission date | Recruitment status | [ ] Prospectively registered |
|---|---|---|
| 29/11/2006 | No longer recruiting | [ ] Protocol |
| **Registration date** | **Overall study status** | [ ] Statistical analysis plan |
| 28/02/2007 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [ ] Individual participant data |
| 25/04/2014 | Musculoskeletal Diseases | |

**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**

Version 2

# Study information

### Scientific Title

### Acronym
EFALL

### Study objectives
Epidural fentanyl is not more effective at controlling post-operative pain than current standard analgesic techniques.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Newcastle and North Tyneside Local Research Ethics Committee on 11/10/2006 (ref: 2 06/Q0906 /126)

### Study design
Randomised controlled single blinded study

### 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
Degenerative lumbar canal stenosis

### Interventions
Single bolus intraoperative epidural fentanyl (100 micrograms) versus best alternative medical care in patients following lumbar laminectomy.

### Intervention Type
Drug

### Phase
Not Specified

### Drug/device/biological/vaccine name(s)
Fentanyl

### Primary outcome measure
Post-operative pain score, day one and day two.

### Secondary outcome measures
1. Length of post-operative hospital stay
2. Post-operative analgesia requirements
3. Side effects:
a. urinary retention
b. nausea
c. vomiting
d. pruritis

### Overall study start date
01/12/2006

### Completion date
30/11/2007

## Eligibility

### Key inclusion criteria
1. Having a lumbar laminectomy for degenerative canal stenosis
2. 18 years or older
3. Able to give informed consent for this trial

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Not Specified

### Target number of participants
100

### Key exclusion criteria
1. There is a Cerebrospinal Fluid (CSF) leak or the dura is opened
2. Contraindication to fentanyl as follows:
a. respiratory depression
b. obstructive airways disease
c. concurrent administration with monoamine oxidase inhibitors, or within two weeks of their discontinuation

d. known intolerance to fentanyl
3. Vulnerable group or unable to consent

**Date of first enrolment**
01/12/2006

**Date of final enrolment**
30/11/2007

# Locations

**Countries of recruitment**
England

United Kingdom

**Study participating centre**
**Department of Neurosurgery**
Cambridge
United Kingdom
CB2 2QQ

# Sponsor information

**Organisation**
Addenbrooke's Hospital (UK)

**Sponsor details**
c/o Dr John Bradley
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**Sponsor type**
Hospital/treatment centre

**Website**
http://www.addenbrookes.org.uk/

**ROR**
https://ror.org/055vbxf86

# Funder(s)

**Funder type**
Hospital/treatment centre

**Funder Name**
The costs of this trial are minimal. They will mostly be covered by internal department funds from the Department of Neurosurgery at Addenbrookes Hospital (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

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 01/08/2012 | | Yes | No |