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

**Submission date**
29/11/2006

**Recruitment status**
No longer recruiting

**Registration date**
28/02/2007

**Overall study status**
Completed

**Last Edited**
25/04/2014

**Condition category**
Musculoskeletal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

**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**
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

## Study type(s)
Treatment

## 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(s)
Post-operative pain score, day one and day two.

## Key secondary outcome(s))
1. Length of post-operative hospital stay
2. Post-operative analgesia requirements
3. Side effects:
a. urinary retention
b. nausea

c. vomiting
d. pruritis

### 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

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Sex
Not Specified

### 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
United Kingdom

England

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

# Sponsor information

**Organisation**
Addenbrooke's Hospital (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

**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 |