

A randomised controlled study of Epidural Fentanyl Analgesia following Lumbar Laminectomy

Submission date 29/11/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 28/02/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 25/04/2014	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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/055vbx86>

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