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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)

Primary study design
Interventional

Study design
Randomised controlled single blinded study

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