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Comparision of epidural versus parental analgesia after colorectal surgery

Submission date 12/09/2003	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 12/09/2003	**Overall study status** Completed	
Last Edited 01/11/2013	**Condition category** Surgery	

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
N0084120704

Study information

Scientific Title

Study objectives
To evaluate the optimal method of pain control after such surgery.

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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Surgery: Colorectal

Interventions
Randomised controlled trial comparing
1. Morphine in a drip
2. Morphine in a drip plus ketamine infusion
3. Epidural analgesia in the spine

Currently pain relief is provided by the patient having a button to press to deliver themselves some pain relieving drug. Every hour a nurse will check the patient and observe to make sure the patient is alright and happy with the pain relief. The nurse will ask a few questions on the quality of pain relief. The patient will be asked to do some deep breathing and to cough to aid this assessment.

Intervention Type
Procedure/Surgery

Phase

Not Applicable

Primary outcome measure
The patient will receive one of three pain control regimes:
1. Morphine in a drip
2. Morphine in a drip plus ketamine infusion
3. Epidural analgesia in their back (spine).

The study is to compare the quality and quantity of pain relief, side effects and satisfaction with different drugs and methods of delivery.

Secondary outcome measures
Not provided at time of registration

Overall study start date
22/03/2002

Completion date
01/12/2004

Eligibility

Key inclusion criteria
297 Samples are required. Normal post-operative analgesic requirements with some patients requiring ketamine. Input from pain management team.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
297

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
22/03/2002

Date of final enrolment
01/12/2004

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Academic Surgical Unit
Cottingham, East Yorkshire
United Kingdom
HU16 5JQ

Sponsor information

Organisation
Department of Health (UK)

Sponsor details
Richmond House
79 Whitehall
London
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SW1A 2NL

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Research organisation

Funder Name
The North and South Bank Research and Development Consortium (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