Comparision of epidural versus parental analgesia after colorectal surgery

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Mr Edward Smyth

Contact details

Academic Surgical Unit Castle Hill Hospital Castle Rd Cottingham, East Yorkshire United Kingdom HU16 5JQ +44 (0)1482 875 875

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

Kev 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 United Kingdom 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 summaryNot provided at time of registration