

Does continuous rectal sheath block decrease postoperative opioid requirement?

Submission date 12/09/2003	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 12/09/2003	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 16/01/2014	Condition category Signs and Symptoms	☐ Individual participant data ☐ Record updated in last year

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
N0283122688

Study information

Scientific Title

Study objectives

Does the intermittent infiltration of 0.25% bupivacaine delivered by an epidural catheter into the rectus sheath decrease the opioid requirement postoperatively after a midline laparotomy?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Single centre prospective randomised controlled trial

Primary study design

Interventional

Study type(s)

Not Specified

Health condition(s) or problem(s) studied

Signs and Symptoms: Pain, nausea, vomiting, itching

Interventions

1. 0.25% Bupivacaine
2. Saline

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

bupivacaine

Primary outcome(s)

The primary outcome measure will be the total amount of opiate used in the intravenous patient controlled analgesia (IVPCA) in the first 48 h.

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Key secondary outcome(s)

Secondary outcome measures will be forced expiratory volume in one second (FEV1) and forced vital capacity (FVC) at 24 and 48 h, the number of episodes of nausea, vomiting, itching, the sedation score, and respiratory rate, the time to passage of flatus and the length of hospital stay.

Completion date

20/06/2004

Eligibility

Key inclusion criteria

40 consenting patients due to undergo a laparotomy.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

20/04/2002

Date of final enrolment

20/06/2004

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

Worthing & Southlands Hospitals NHS Trust

Worthing, West Sussex

United Kingdom

BN11 2DH

Sponsor information**Organisation**

Department of Health (UK)

Funder(s)

Funder type

Industry

Funder Name

Commercial educational grant

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration