ISRCTN46452718 https://doi.org/10.1186/ISRCTN46452718

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

Contact name
Mr William Woods

Contact details
Worthing & Southlands Hospitals NHS Trust
Worthing Hospital
Lyndhurst Road
Worthing, West Sussex
United Kingdom
BN11 2DH

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

Primary study design
Interventional

Study design
Single centre prospective randomised controlled trial

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.
.

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