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 [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 12/09/2003	**Overall study status** Completed	
Last Edited 16/01/2014	**Condition category** Signs and Symptoms	

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

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

Secondary outcome measures
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.

Overall study start date
20/04/2002

Completion date
20/06/2004

Eligibility

Key inclusion criteria
40 consenting patients due to undergo a laparotomy.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
40

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
England

United Kingdom

Study participating centre

Worthing & Southlands Hospitals NHS Trust
Worthing, West Sussex
United Kingdom
BN11 2DH

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
Industry

Funder Name
Commercial educational grant

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