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Effects of subfascial infiltration of 0.25% bupivacaine versus N/saline in elective abdominal surgery: a randomised controlled trial.

Submission date 30/09/2004	**Recruitment status** Stopped	[_] Prospectively registered [_] Protocol
Registration date 30/09/2004	**Overall study status** Stopped	[_] Statistical analysis plan [_] Results
Last Edited 25/10/2011	**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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0234126586

Study information

Scientific Title
Effects of subfascial infiltration of 0.25% bupivacaine versus N/saline in elective abdominal surgery: a randomised controlled trial.

Study objectives
The effects of subfascial infiltration of 0.25% bupivacaine versus N/saline in elective abdominal surgery: a randomised controlled trial.

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)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Signs and Symptoms: Post-operative pain

Interventions
Patients will undergo a simple non-invasive pulmonary function test carried out at the patients bedside and repeated each morning for the first 7 days postoperatively.

Added August 2008: trial stopped.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Surgery pain scores.

Secondary outcome measures
Not provided at time of registration

Overall study start date
30/05/2003

Completion date
30/10/2003

Reason abandoned (if study stopped)
Lack of staff

Eligibility

Key inclusion criteria
All patients who require abdominal surgery (midline laparotomy) and are aged between 18-90 will be entered into the study excluding the following: History of drug abuse, chronic pain, regular medication with opioids/non-steroidal anti-inflammatory drugs (NSAIDs), diabetes, morbid obesity, unable to use patient controlled analgesia (PCA). A total of 80 patients will be studied, 40 in each group (those receiving a placebo, and those receiving 0.25% bupivacaine).

Participant type(s)
Patient

Age group
Not Specified

Lower age limit
18 Years

Upper age limit
90 Years

Sex
Not Specified

Target number of participants
80

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
30/05/2003

Date of final enrolment
30/10/2003

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Surgery
Bristol
United Kingdom
BS16 1ND

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
North Bristol NHS Trust (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