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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

Protocol serial number
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

Study type(s)
Not Specified

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(s)
Surgery pain scores.

Key secondary outcome(s))
Not provided at time of registration

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

Healthy volunteers allowed
No

Age group
Not Specified

Lower age limit
18 years

Upper age limit
90 years

Sex
Not Specified

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
United Kingdom

England

Study participating centre
Department of Surgery
Bristol

United Kingdom
BS16 1ND

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Government

Funder Name
North Bristol NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration