

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 30/09/2004	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 25/10/2011	Condition category Signs and Symptoms	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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