

Which is better: paravertebral (PV) or interpleural (IP) bupivacaine for breast surgery?

Submission date 12/09/2003	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/09/2003	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 04/02/2014	Condition category Surgery	<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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0072091240

Study information

Scientific Title

Study objectives

Not provided at time of registration

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)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Surgery: Breast

Interventions

Randomisation to two groups, standardised general anaesthetic, IP or PV block, recovery, test for failure, observed for pain, nausea and vomiting (N&V), patient-controlled analgesia (PCA) morphine consumption.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Bupivacaine

Primary outcome measure

1. Visual Analogue Pain Scores at rest and on movement
2. Nausea scale and vomiting episodes
3. Morphine and other analgesic consumption

4. Time to morphine demand

5. Hospital stay

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/04/2001

Completion date

01/07/2003

Eligibility

Key inclusion criteria

All patients having major breast surgery.

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

Proposed 40 patients - 20 in each group

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/04/2001

Date of final enrolment

01/07/2003

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Countess of Chester NHS Trust

Chester

United Kingdom
CH3 1UL

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

Government

Funder Name

Countess of Chester Hospital 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