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

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 04/02/2014	**Condition category** Surgery	

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