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Effectiveness of Bupivacaine in Pain Management following Breast Augmentation

Submission date 28/09/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 28/09/2007	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 30/08/2012	**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
N0072186040

Study information

Scientific Title

Study objectives

1. Is bupivacaine better than placebo in reducing the post-operative pain?
2. Does bupivacaine used as supplement reduce the opiate dosage?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised double blind controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Signs and Symptoms: Pain

Interventions
A blinded member of the team will assess the pain at 2,4 and hours after the operation. Length of hospital stay is also recorded.
The data analysis will take place at Countess of Chester Hospital (COCH). The research team at COCH will analyse the data using SPSS software.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Bupivacaine

Primary outcome(s)
Is bupivacaine superior than placebo in pain control following breast augmentation?

Key secondary outcome(s))
1. Does bupivacaine reduce opiate requirement?
2. Does it reduce hospital stay?
3. Does it reduce the incidence of opiate related adverse effects?

Completion date
01/08/2009

Eligibility

Key inclusion criteria
1. Patients undergoing breast augmentation
2. For correction of congenital anomaly or asymmetry. This group is usually young population, so usually not associated with co-morbid conditions which might complicate result.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
1. Patients undergoing augmentation following mastectomy or as part of other reconstruction
2. Patients with multiple co-morbidity

Date of first enrolment
01/08/2006

Date of final enrolment
01/08/2009

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Countess of Chester Hospital NHS Foundation Trust
Chester
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CH2 1UL

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Funder(s)

Funder type
Government

Funder Name
Countess of Chester NHS Foundation Trust

Funder Name
NHS R&D Support Funding

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration