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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
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
N0072186040

Study information

Scientific Title

Study hypothesis
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Condition
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 measure
Is bupivacaine superior than placebo in pain control following breast augmentation?

Secondary outcome measures
1. Does bupivacaine reduce opiate requirement?
2. Does it reduce hospital stay?
3. Does it reduce the incidence of opiate related adverse effects?

Overall study start date
01/08/2006

Overall study end date
01/08/2009

Eligibility

Participant 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

Age group
Adult

Sex
Female

Target number of participants
Total 50; 25 in each group.

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

Recruitment start date
01/08/2006

Recruitment end date
01/08/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Countess of Chester Hospital NHS Foundation Trust
Chester
United Kingdom
CH2 1UL

Sponsor information

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

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
London
United Kingdom
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dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Countess of Chester NHS Foundation Trust

Funder Name
NHS R&D Support Funding

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