

Effectiveness of Bupivacaine in Pain Management following Breast Augmentation

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| Submission date 28/09/2007 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 28/09/2007 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 30/08/2012 | 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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 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

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

Age group

Adult

Sex

Female

Target number of participants

Total 50; 25 in each group.

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**

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
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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