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A double blind randomised controlled trial examining the efficacy of local anaesthesia in reducing post-operative pain when performing breast reductions

Submission date 12/09/2003	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 12/09/2003	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 13/10/2017	**Condition category** Surgery	[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0021122446

Study information

Scientific Title
A double blind randomised controlled trial examining the efficacy of local anaesthesia in reducing post-operative pain when performing breast reductions

Study objectives
The aim is to establish whether infiltrating the breast with a very low concentration of local anaesthetic solution reduces post-operative pain following breast reducing surgery.

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)
Not specified

Study type(s)
Not Specified

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Interventions
Following induction of anaesthesia, 500 ml of a solution of adrenaline in normal saline (control) or bupivicaine plus adrenaline in normal saline (experimental) will be infiltrated into each breast. Both the patient and the surgeon will be blinded to the patient's trial group allocation.

Intervention Type
Procedure/Surgery

Phase

Not Specified

Primary outcome measure
Patient's post-operative use of morphine using a PCA (patient controlled analgesia) device.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/05/2002

Completion date
01/05/2004

Eligibility

Key inclusion criteria
Women aged 18 and over attending the Plastic Surgery Department at Wexham Park Hospital for breast reduction. Patient's with a history of substance abuse or who have a known allergy to the agents used will be excluded.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
Not provided at time of registration

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/05/2002

Date of final enrolment
01/05/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Heatherwood and Wexham Park Hospitals NHS Trust
Slough
United Kingdom
SL2 4HL

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
Hospital/treatment centre

Funder Name
Heatherwood and Wexham Park Hospitals 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