

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	<input type="checkbox"/> Prospectively registered
Registration date 12/09/2003	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 13/10/2017	Condition category Surgery	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<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

Protocol serial number
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

Study type(s)

Not Specified

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 bupivacaine 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(s)

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

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Female

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**

United Kingdom

England

Study participating centre

Heatherwood and Wexham Park Hospitals NHS Trust

Slough

United Kingdom

SL2 4HL

Sponsor information**Organisation**

Department of Health (UK)

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Heatherwood and Wexham Park Hospitals NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration