

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

<b>Submission date</b> 12/09/2003	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 12/09/2003	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 13/10/2017	<b>Condition category</b> 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

### Contact name

Mr Christopher Khoo

### Contact details

Heatherwood and Wexham Park Hospitals NHS Trust  
Department of Plastic Surgery  
Wexham Park Hospital  
Wexham Street  
Slough  
United Kingdom  
SL2 4HL

## 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 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 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