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Efficacy of ultrasound guided retro-mammary blocks for post-operative pain control in patients undergoing breast surgery

Submission date 29/09/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 29/09/2006	**Overall study status** Completed	
Last Edited 20/07/2012	**Condition category** Surgery	

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
N0190161953

Study information

Scientific Title

Study objectives
To evaluate the analgesic effect of local anaesthetic in the retro-mammary space under ultrasound guidance.

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)
Hospital

Study type(s)
Not Specified

Participant information sheet

Health condition(s) or problem(s) studied
Surgery: Breast

Interventions
Ultrasound guided retro-mammary blocks vs normal practice

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure
The total analgesic requirements during the first 24 hours post-operatively

Secondary outcome measures
Not provided at time of registration

Overall study start date
30/07/2005

Completion date
31/12/2006

Eligibility

Key inclusion criteria
40 cases (90% power, p= 0.05) with following criteria:
1. Male and female patients having unilateral or bilateral breast surgery not involving the axilla
2. Age 16-70

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
40

Key exclusion criteria
1. No consent
2. Allergy to local anaesthetic
3. Clotting disorder

Date of first enrolment
30/07/2005

Date of final enrolment
31/12/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The Queen Victoria Hospital NHS Trust
East Grinstead
United Kingdom
RH19 3DZ

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type
Government

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

Funder(s)

Funder type
Government

Funder Name
Queen Victoria Hospital NHS Trust (UK), 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