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The effectiveness of peri-operative use of human surgical sealant (Quixil) in reducing the post-operative seroma formation in breast cancer patients

Submission date
30/09/2004

Registration date
30/09/2004

Last Edited
05/12/2014

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0523136364

Study information

Scientific Title
The effectiveness of peri-operative use of human surgical sealant (Quixil) in reducing the post-operative seroma formation in breast cancer patients

Study objectives
The trial proposes to establish the usefulness of 'Quixil' in reducing the incidence of post-operative seroma in breast cancer operations

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)
Treatment

Participant information sheet

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

Interventions
1. Quixil
2. No Quixil

Intervention Type
Procedure/Surgery

Primary outcome measure
Reduction in seroma formation of more than 30%

Secondary outcome measures

Not provided at time of registration

Overall study start date
01/08/2003

Completion date
01/12/2004

Eligibility

Key inclusion criteria
100 patients undergoing mastectomy or wide local excision with axillary clearance for biopsy proven breast cancer. 50 to each arm.

Participant type(s)
Patient

Age group
Not Specified

Sex
Female

Target number of participants
100

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/08/2003

Date of final enrolment
01/12/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Good Hope Hospital
Birmingham
United Kingdom
B75 7RR

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

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

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Good Hope Hospital 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