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The role of Quixil Human Surgical Sealant in Mastectomy and Wide Local Excision with Axillary Clearance

Submission date 29/09/2006	**Recruitment status** Stopped	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 29/09/2006	**Overall study status** Stopped	
Last Edited 17/08/2012	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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United Kingdom
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0265160831

Study information

Scientific Title

Study objectives
Does the use of Quixil surgical sealant reduce the post-operative blood and lymph loss, thereby reducing the time to drain removal, shortening the post-operative hospital stay?

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

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

Interventions
Patients undergoing either mastectomy or Wide Local Excision with axillary clearance / level 1&2 sampling, will be randomised to either receive an application of Quixil surgical sealant at wound closure or standard wound closure. Quixil will he spray applied to all wound surfaces prior to closure and drain insertion, in the group randomised to receive this arm of treatment. Two low vacuum suction drains will be placed, one in the axilla and the other in the chest wound. Vacuum will be applied after wound closure or 5 minutes, which ever is longer.

Time to drain removal and discharge from hospital, and drain output volumes will be the primary end points. Patient's demographic data and operative data will be collected to ensure standardisation of the two randomised groups. Any operative and postoperative complications will be recorded including wound seroma formation. Patients will be followed up in the out patients department to examine the wound at fourteen days.

17/08/2012: Please note that this study was stopped in 2008 due to issues with participant recruitment

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Quixil

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
19/09/2003

Completion date
19/09/2008

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
40 patient volunteers with proven breast cancer already booked to undergo surgery. Inclusion Criteria:
1. Patients with breast cancer undergoing either mastectomy or WLE and axillary clearance
2. Patients able and willing to sign the Patient Informed Consent Form and agree to the study requirements
3. Patients with a normal coagulation profile

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
40

Key exclusion criteria

1. Patients with signs and/or symptoms of systemic and/or local infection
2. Patients having a re-operation
3. Patients with suspected inflammatory breast cancer
4. Patients requiring concomitant surgery
5. Patients taking any form of anticoagulants

Date of first enrolment
19/09/2003

Date of final enrolment
19/09/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
GI Surgery
Birmingham
United Kingdom
B15 2TH

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
University Hospital Birmingham 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