

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	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 30/09/2004	Overall study status Completed	☐ Protocol
Last Edited 05/12/2014	Condition category Cancer	☐ 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

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Cancer: Breast

Interventions

1. Quixil
2. No Quixil

Intervention Type

Procedure/Surgery

Primary outcome(s)

Reduction in seroma formation of more than 30%

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Female

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**

United Kingdom

England

Study participating centre

Good Hope Hospital

Birmingham

United Kingdom

B75 7RR

Sponsor information**Organisation**

Department of Health

Funder(s)**Funder type**

Hospital/treatment centre

Funder Name

Good Hope Hospital NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration