

Prospective, randomised study comparing quilting and a drain with a drain only on the incidence of seroma formation in the back wound after Latissimus Dorsi breast reconstruction (LDBR)

Submission date 30/09/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/09/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 28/02/2020	Condition category Surgery	<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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0264132545

Study information

Scientific Title

Prospective, randomised study comparing quilting and a drain with a drain only on the incidence of seroma formation in the back wound after Latissimus Dorsi breast reconstruction (LDBR)

Study objectives

To do a prospective randomised comparison of the seroma rate in the back wound between drain and quilting versus drains alone.

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

Surgery: Breast reconstruction

Interventions

1. Quilting suture and drain
2. Drain only

Intervention Type

Procedure/Surgery

Phase

Not Applicable

Primary outcome measure

Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/08/2001

Completion date

01/08/2004

Eligibility

Key inclusion criteria

Not provided at time of registration

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

Not provided at time of registration

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/08/2001

Date of final enrolment

01/08/2004

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Level 1, The Old Building

Bristol

United Kingdom

BS2 8HW

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

Government

Funder Name

United Bristol Healthcare 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