

QUEST Trial B - Quality of life following mastectomy and breast reconstruction

Submission date 15/12/2009	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 06/01/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 26/10/2022	Condition category Cancer	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

<https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-comparing-how-women-feel-about-themselves-after-having-immediate-or-delayed-breast-reconstruction-surgery-quest-b>

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

CRUK/08/027

Study information

Scientific Title

A multicentre randomised trial to assess the impact of the timing of breast reconstruction on quality of life following mastectomy

Acronym

QUEST Trial B

Study objectives

1. To determine the acceptability and experience of randomisation amongst patients and healthcare professionals (surgeons and breast care nurses) and hence the acceptability of a randomised clinical trial in breast reconstruction
2. To evaluate Health Related Quality of Life (HRQL)

As of 21/09/2011 the overall trial start and end dates for this trial have been updated. The previous start date was 30/04/2010 and the previous end date was 31/12/2011.

Ethics approval required

Old ethics approval format

Ethics approval(s)

South West 2 Research Ethics Committee on 11/09/2010 (ref: 10/H0206/42)

Study design

Phase III multicentre parallel randomised feasibility trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Breast cancer

Interventions

Group 1: immediate autologous extended tissue based LDBR (immediate autologous extended latissimus dorsi [ALD])

Group 2: staged-delayed autologous extended tissue based LDBR (delayed ALD).

The group allocated to immediate reconstruction will have one surgical intervention at the time of mastectomy. The patients in the stage-delayed group will have a two stage reconstruction. The first stage is carried out at the time of mastectomy and the second surgical intervention will be delayed until 6 months post-mastectomy in patients receiving radiotherapy alone and approx 12 months post-mastectomy in patients receiving both chemo- and radiotherapy. Duration of follow up is 5 years in both groups.

Intervention Type

Procedure/Surgery

Primary outcome(s)

1. The number of eligible women who accept randomisation and their subsequent treatment allocation
2. The rationale for women declining randomisation as assessed through the Patient Views on QUEST questionnaire (PVQ)
3. The perceptions of surgeons and breast care nurses regarding equipoise evidence relating to cosmetic appearance, complications and quality of life outcomes through Perceptions of Equipoise Evidence and Randomisation Survey (PEERS)

Key secondary outcome(s)

Health-related quality of life outcomes, measured at change from baselines to each of the follow-up assessments at 3, 6, 9, 12, 18, 24, 36, 48 and 60 months between allocated treatment groups

Completion date

31/12/2012

Eligibility

Key inclusion criteria

1. Women requiring a mastectomy and electing to undergo latissimus dorsi breast reconstruction (LDBR) following a diagnosis of invasive primary breast cancer or ductal carcinoma in situ (DCIS)
2. Technically suitable for a stage delayed autologous extended tissue-based latissimus dorsi (LD) procedure (this includes patients agreeable to a Wise or central reduction pattern reconstruction and a planned contralateral symmetrisation procedure if there is not sufficient volume to reconstruct the breast to its native size)
3. Pre-operative evaluation of the breast and axilla suggest that post-operative radiotherapy (RT) is anticipated according to local RT policy
4. Patient does not express a preference regarding procedure type
5. The capacity to understand the patient information sheet and ability to provide written informed consent
6. The capacity to understand and complete the self report HRQL and General Nordic Questionnaire for Psychological and Social Factors at Work (QPS) questionnaires
7. Physical fitness as per the pre-operative evaluations (electrocardiogram [ECG], chest X-ray [CXR], blood biochemistry)
8. Aged between 25 and 75 years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

1. Prophylactic or risk-reducing surgery (i.e. no malignant or pre-malignant pathology such as lobular carcinoma in situ [LCIS])
2. Previous radiotherapy to the breast
3. Bilateral synchronous pathology
4. Loco-regional recurrence
5. Previous wide local excision requiring completion mastectomy
6. Pregnancy as confirmed on blood tests or ultrasound examination
7. Evidence of distant metastases as diagnosed by chest X-ray, bone scan, liver ultrasound scan (USS) or computed tomography (CT) chest/abdomen and magnetic resonance imaging (MRI)
8. Previous malignancy except basal cell carcinoma (BCC) or squamous cell carcinoma (SCC) of the skin
9. Significant other clinical risk factors and co-morbidities e.g. body mass index (BMI), diabetes, smoker according to local policy

Date of first enrolment

09/07/2011

Date of final enrolment

14/12/2012

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Bristol Royal Infirmary

Bristol

United Kingdom

BS2 8HW

Sponsor information

Organisation

University Hospitals of Bristol NHS Foundation Trust (UK)

ROR

<https://ror.org/04nm1cv11>

Funder(s)

Funder type

Charity

Funder Name

Cancer Research UK (CRUK) (UK)

Alternative Name(s)

CR_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Funder Name

BUPA Foundation (UK)

Alternative Name(s)

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Funder Name

University Hospitals of Bristol NHS Foundation Trust (UK) - Above and Beyond Charities

Funder Name

Allergan Aesthetics (UK)

Funder Name

Royal College of Surgeons of England (UK)

Alternative Name(s)

RCS England, RCS ENG, The Royal College of Surgeons of England, RCS

Funding Body Type

Private sector organisation

Funding Body Subtype

Universities (academic only)

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2015		Yes	No
Plain English results			26/10/2022	No	Yes