

# QUEST Trial A - Quality of life following mastectomy and breast reconstruction

<b>Submission date</b> 15/12/2009	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 06/01/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 04/04/2022	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

<https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-how-women-feel-about-themselves-after-breast-reconstruction-during-surgery-breast-cancer-quest-a>

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

## Study information

### Scientific Title

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

### Acronym

QUEST Trial A

### Study objectives

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.

On 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, 11/09/2010, ref: 10/H0206/41

### Study design

Phase III multicentre parallel randomised feasibility trial

### Primary study design

Interventional

### Secondary study design

Randomised parallel 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

Breast cancer

### Interventions

Patients will be allocated in a 1:1 ratio to either immediate autologous extended latissimus dorsi (ALD) breast reconstruction or immediate implant assisted latissimus dorsi (LDI) breast reconstruction. Duration of follow-up is 5 years in both groups.

## **Intervention Type**

Procedure/Surgery

## **Primary outcome measure**

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)

## **Secondary outcome measures**

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

## **Overall study start date**

01/08/2011

## **Completion date**

31/12/2012

# **Eligibility**

## **Key inclusion criteria**

1. Any 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. Pre-operative evaluation of the breast and axilla suggest that post-operative radiotherapy is not anticipated according to local radiotherapy (RT) policy
3. Patient is technically suitable for an autologous extended LD procedure or agreeable to a reduction mammoplasty and planned contralateral reduction
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 reported Health Related Quality of Life (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

## **Age group**

Adult

**Sex**

Female

**Target number of participants**

55

**Total final enrolment**

17

**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. Previous wide local excision (requiring completion mastectomy)
5. Loco-regional recurrence
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/or magnetic resonance imaging (MRI)

**Date of first enrolment**

01/08/2011

**Date of final enrolment**

31/12/2012

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Bristol Royal Infirmary**

Bristol

United Kingdom

BR2 8HW

## **Sponsor information**

**Organisation**

University Hospitals of Bristol NHS Foundation Trust (UK)

**Sponsor details**

Trust Headquarters  
Marlborough Street  
Bristol  
England  
United Kingdom  
BS1 3NU

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.uhbristol.nhs.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, 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

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Associations and societies (private and public)

**Location**

United Kingdom

## Results and Publications

**Publication and dissemination plan**

Not provided at time of registration

**Intention to publish date****Individual participant data (IPD) sharing plan**

Not provided at time of registration

**IPD sharing plan summary**

Not provided at time of registration

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
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<a href="#">Results article</a>	results	01/01/2015		Yes	No
<a href="#">Results article</a>	results	02/09/2016		Yes	No
<a href="#">Plain English results</a>			04/04/2022	No	Yes