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

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered		
15/12/2009		☐ Protocol		
Registration date	Overall study status Completed	Statistical analysis plan		
06/01/2010		[X] Results		
Last Edited	Condition category	Individual participant data		
04/04/2022	Cancer			

#### 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

Dr Zoe Winters

#### Contact details

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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 lattissimus dorsi (ALD) breast reconstruction or immediate implant assisted lattissimus 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?

Results article	results	01/01/2015		Yes	No
Results article	results	02/09/2016		Yes	No
Plain English results			04/04/2022	No	Yes