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

Submission date 15/12/2009	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 06/01/2010	**Overall study status** Completed	
Last Edited 26/10/2022	**Condition category** Cancer	

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
Dr Zoe Winters

Contact details
Bristol Royal Infirmary
Clinical Sciences
South Bristol
Level 7, Marlborough Street
Bristol
United Kingdom
BS2 8HW

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled 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
Group 1: immediate autologous extended tissue based LDBR (immediate autologous extended lattissimus 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 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 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

Overall study start date
07/07/2011

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

Age group
Adult

Sex
Female

Target number of participants
55

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
England

United Kingdom

Study participating centre
Bristol Royal Infirmary
Bristol
United Kingdom
BS2 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
Plain English results			26/10/2022	No	Yes