ISRCTN25603476 https://doi.org/10.1186/ISRCTN25603476

Sensate DIEP flaps - assessment of breast sensation on quality of life and body image

Submission date 29/09/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 29/09/2006	**Overall study status** Completed	
Last Edited 29/01/2015	**Condition category** Surgery	

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
N0265166244

Study information

Scientific Title

Sensate DIEP flaps - assessment of breast sensation on quality of life and body image

Study objectives
1. To assess how important breast sensation is to patients undergoing breast reconstruction both pre and post operatively and the degree that this impacts on patient quality of life and body image
2. To assess the recovery of sensation in a breast reconstructed with abdominal skin and nerve reattachment, and to compare this to a breast reconstructed with abdominal skin that has not had the nerve reattached, and a bust reconstructed with skin/muscle from the back

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
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Surgery: Breast

Interventions
Patients preparing for an excision of breast cancer and reconstruction are seen pre-operatively and followed up in our breast reconstruction clinic. These patients are counselled as to the expected loss of breast sensation following surgery. They are then offered a choice of reconstructive options, which include:
1. Implant only
2. Skin and muscle from the back
3. Skin and muscle from the stomach (+ or - nerve reattachment

We intend to ask all patients within these three groups how important they think breast sensation is to them before the operation. We also wish to obtain validated measures of anxiety and depression and body image,
Following the Operation. We will repeat the questionnaire and body Image assessment to

establish how much this does impact upon their everyday life and how much sensory return they achieve. This will be repeated at each clinic visit (3 monthly) for 1 year.

The patients who are having reconstructions from their abdominal skin and muscle will be randomised into two groups: those receiving nerve reattachment and those not having nerve reattachment. At present the nerve is reattached occasionally, if it is deemed easy 10 perform intra-operatively. The vast majority of patients do not have the nerve reattached. It will add 30-60 minutes to the operation time. The study will be double blinded.

The questionnaire is a VAS addressing the impact of sensation upon quality of life. The wording has been finalised after speaking to a group of patients attending the clinic.

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
24/06/2005

Completion date
24/03/2008

Eligibility

Key inclusion criteria
All patients attending the breast reconstruction clinic for one of the three types of breast reconstruction will be seen at the clinic and asked if they wish to participate in the research. They will not have to attend any extra clinics. The questionnaire will simply be given out whilst they are in the waiting room and can be completed before they are called in to see the doctor. Those patients who are having reconstruction with abdominal skin and muscle will be informed of the procedure to reattach the nerve and asked if they would be happy to be randomised into nerve reattachment or no nerve reattachment.

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
Not provided at time of registration

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
24/06/2005

Date of final enrolment
24/03/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Selly Oak Hospital
Birmingham
United Kingdom
B29 6JD

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
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Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
University Hospital Birmingham NHS Trust (UK)

Funder Name
NHS R&D Support Funding

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