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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

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(s)
Not provided at time of registration

Key secondary outcome(s)
Not provided at time of registration

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

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

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
United Kingdom

England

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

Funder(s)

Funder type
Government

Funder Name
University Hospital Birmingham NHS Trust (UK)

Funder Name
NHS R&D Support Funding

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration