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A randomised controlled trial of duct endoscopy as an adjunct to standard surgery for pathological nipple discharge

Submission date 29/09/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 29/09/2006	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 15/03/2017	**Condition category** Cancer	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
http://www.cancerhelp.org.uk/trials/a-study-looking-at-changes-inside-the-breast-ducts-of-women-who-have-nipple-discharge

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0258175375

Study information

Scientific Title
A randomised controlled trial of duct endoscopy as an adjunct to standard surgery for pathological nipple discharge

Acronym
INTEND II

Study objectives
To clarify the future role of the intraduct approach in a systematic manner by a randomised controlled trial that would establish whether this approach should be encouraged or disparaged.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Royal Marsden Local Research Ethics Committee (LREC), 20/03/2006, ref: 06/Q0801/29

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

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
Cancer: Breast

Interventions
Randomised test intervention vs standardized intervention, non-blinded (Phase III)

Intervention Type
Other

Phase
Phase III

Primary outcome measure
1. Successful visualisation of lesions in the duct endoscopy group correlating to pathological findings
2. Size of the tissue resection in the DE versus no DE group

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/03/2006

Completion date
31/03/2011

Eligibility

Key inclusion criteria
1. 100 RMH female patients undergoing duct excision biopsy for the routine management of PND with symptoms of either spontaneous symptomatic discharge from a single duct
2. Patients with bloodstained nipple discharge or abnormal cytology of the duct fluid
3. Routine preoperative screening: mammogram and ultrasound, where appropriate, in accordance with the breast unit protocol
4. Have not had previous periareolar incisions or surgical biopsy in the same quadrant as the target lesion
5. Have intact nipples
6. Have an ECOG score of 0-1
7. Able to give informed consent

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
100

Key exclusion criteria
1. Currently pregnant or pregnant within the past 6 months
2. Currently lactating or lactated within the past 6 months
3. Have received chemotherapy within the past 6 months
4. Have an active infection in the breast
5. Have a previous history of breast cancer (including invasive carcinoma, Pagets disease and DCIS)

6. Have silicone injections or breast implants (pre-pectoral) that disrupt the ductal architecture of the breast
7. Have prior breast surgery that may cause the ductal system not to communicate with the nipple, as determined by the clinician
8. Be unwilling or unable to provide written informed consent

Date of first enrolment
01/03/2006

Date of final enrolment
31/03/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Breast Diagnostic Unit
London
United Kingdom
SW3 6JJ

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
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SW1A 2NL
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dhmail@doh.gsi.org.uk

Sponsor type
Government

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

Funder(s)

Funder type
Government

Funder Name
The Royal Marsden NHS Foundation Trust (UK), 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