

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

Contact name

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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**

United Kingdom

England

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

Funder(s)

Funder type

Government

Funder Name

The Royal Marsden NHS Foundation Trust (UK), NHS R&D Support Funding

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration