

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

<b>Submission date</b> 29/09/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 29/09/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 15/03/2017	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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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### Contact details

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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

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+44 (0)20 7307 2622

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