# Duct endoscopy in the evaluation of breast cancer and surgical margins

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
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
15/03/2017	Cancer	<ul><li>Record updated in last year</li></ul>

#### Plain English summary of protocol

http://www.cancerhelp.org.uk/trials/a-trial-looking-at-checking-inside-the-breast-ducts-for-cancer-cells-during-surgery-intend-1

# Contact information

### Type(s)

Scientific

#### Contact name

Mr Gerald Gui

#### Contact details

Breast Diagnostic Unit Royal Marsden NHS Trust Fulham Road London United Kingdom SW3 6JJ +44 (0)20 7487 5558 gerald.gui@rmh.nhs.uk

# Additional identifiers

Protocol serial number

N0258175369

# Study information

#### Scientific Title

Duct endoscopy in the evaluation of breast cancer and surgical margins

#### **Acronym**

INTEND I (intraoperative endoscopic evaluation of duct epithelium)

#### **Study objectives**

This project seeks to clarify the future role of breast duct endoscopy versus no duct endoscopy as an adjunct to surgery in a randomised controlled trial. The procedure enables cancer duct systems to be directly visualised. We will test an observation that the re-operation rate for margins involved by cancer can be reduced by inspection of the ducts at the time of surgery. We intend to evaluate the feasibility of this approach by assessing whether the ducts that yield fluid, that can be accessed, have an anatomic relationship with the tumour position.

On 17/02/2011 the following changes were made to the trial record:

- 1. The anticipated end date for this trial was changed from 31/12/2009 to 31/08/2011.
- 2. The target number of participants was changed from 150 to 176.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Royal Marsden REC at South London REC Office, St George's University of London, 20/03/2006, ref: 06/Q0801/17

#### Study design

Randomised non-blinded phase III trial

#### Primary study design

Interventional

## Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Cancer: Breast

#### **Interventions**

Test intervention vs standardized intervention

## Intervention Type

Other

#### Phase

Phase III

#### Primary outcome(s)

Duct endoscopy assisted determination of excision margins in breast conservation surgery and its effect on re-excision rates.

#### Key secondary outcome(s))

Added September 2008: laboratory studies on the ductal lavage material obtained.

#### Completion date

31/08/2011

# **Eligibility**

#### Key inclusion criteria

- 1. Female patients undergoing wide local excision determined by standard criteria for the management of needle biopsy-diagnosed DCIS, or clinical stage 1 or 2 breast cancer
- 2. Tumour <3cm, have not had previous periareolar incisions or surgical biopsy in the same quadrant as the target lesion, have intact nipples, have an ECOG score of 0-1
- 3. Able to give consent

#### Participant type(s)

**Patient** 

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Sex

Female

#### Key exclusion criteria

Subjects may not participate in the clinical trial if they meet ANY of the following criteria:

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

#### Date of first enrolment

09/02/2006

#### Date of final enrolment

31/08/2011

## 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

#### **Funder Name**

Breakthrough Breast Cancer

#### Alternative Name(s)

#### **Funding Body Type**

Private sector organisation

#### **Funding Body Subtype**

Other non-profit organizations

#### Location

**United Kingdom** 

## **Results and Publications**

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

**Study outputs** 

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet 11/11/2025 No Yes