

Duct endoscopy in the evaluation of breast cancer and surgical margins

Submission date 29/09/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 29/09/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 15/03/2017	Condition category 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-trial-looking-at-checking-inside-the-breast-ducts-for-cancer-cells-during-surgery-intend-1>

Contact information

Type(s)

Scientific

Contact name

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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