ISRCTN82827389 https://doi.org/10.1186/ISRCTN82827389

Duct endoscopy in the evaluation of breast cancer and surgical margins

Submission date	Recruitment status	[ ] Prospectively registered
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	[ ] 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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

Test intervention vs standardized intervention

Intervention Type
Other

Phase
Phase III

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

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

Overall study start date
09/02/2006

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

Age group
Adult

Sex
Female

Target number of participants
176

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
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
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SW1A 2NL
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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

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

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