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Does intra-operative Marginprobe use reduce re--excision rates?

Submission date 20/02/2017	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 27/03/2017	**Overall study status** Completed	
Last Edited 04/10/2022	**Condition category** Cancer	

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-reducing-further-operations-after-breast-conserving-surgery

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT02774785

Secondary identifying numbers
19495

Study information

Scientific Title
Does intra-operative use of the MarginProbe device reduce the need for further re--excision procedures after conservation surgery for breast cancer?

Study objectives
Study aims:
1. To determine if intraoperative margin assessment after excision of a cancer reduces second operations (re-excision or mastectomy), compared to standard surgical practice by 9 months after primary surgery
2. To determine if the use of the MarginProbe device, after surgical tumour excision and tissue specimen radiography of a breast cancer, reduces rates of further surgical re-excision operations (re-excision or mastectomy), when compared to control/standard practice (whereby the wound is closed after radiography showing clear margins)

Ethics approval required
Old ethics approval format

Ethics approval(s)
North West/Greater Manchester West REC, 05/06/2015, ref: 15/NW/0306

Study design
Randomised; Interventional; Design type: Prevention, Device, Surgery

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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
Breast cancer

Interventions
All surgeons will perform standard wide local excision (BCS) using localisation of the lesion for impalpable lesions where required. Randomization will take place immediately after the main ex-

vivo lumpectomy specimen has been excised, oriented, border marked, inspected, palpated and additional cavity shavings (per visual inspection, palpation and radiology) performed. Patients will be randomised in theatre, by call to the MAHSC CTU, to either standard procedure alone or standard procedure with the use of the MarginProbe device:

Device Arm: Measurements shall be taken with the MarginProbe on the outer final surface of each margin. Once the device has been applied to outer final surface of all margins, all margins with one or more positive readings on it should be shaved from the cavity. The procedure will then be concluded in the routine practice.

Control Arm: The procedure will be concluded in the routine practice.

MarginProbe use starts and ends during the primary lumpectomy procedure. Thus, patient management differs between the two study arms only during the procedure. Following the procedure, pathological assessment and any other patient management aspects are identical for both study arms. The follow-up period for both study arms is 9 months. Follow up visits (month 1, 6 and 9): FACT B +4, HADS and EQ5D Questionnaires and Patient Diary Cards Administered. Photographs for cosmesis completed at baseline and 9 months.

Intervention Type
Other

Primary outcome measure
1. Reduction rates in re-excision procedures are determined by review of pathology reports for all participants to record subsequent surgeries at 9 months post initial surgery
2. Total number of re-excision procedures is determined by review of patient notes, clinical data and pathology reports at 9 months post initial surgery
3. Excision margins determined by review of pathology reports at 9 months post initial surgery

Secondary outcome measures
1. Quality of life measured by using validated self-completion disease specific and generic instruments, FACT-B, HADS, health-related utility (EQ5D) and the body image scale of SABIS administered at baseline (pre-surgery) and postal follow-up at 1, 3 and 9 months post-surgery
2. Cosmetic outcome assessment will be performed by two objective evaluators blinded to arm assignment based on pictures taken under standardized photographic conditions. The scoring will be performed using the validated 4-point Harvard scale. Pictures will be taken at baseline and 9 months post-surgery.
3. Impact of margin assessment on patients and carers will be measured by questionnaires assessing experiences and satisfaction and semi structured interviews exploring concerns, expectations, preferences, satisfaction and awareness of procedural differences. This will be a qualitative sub study of the main trial and timescales are dependent on when this is set up.
4. Clinical and cost effectiveness measured by review of hospital in-patient records and patient diary cards at 1, 3 and 9 months

Overall study start date
24/03/2014

Completion date
12/12/2020

Eligibility

Key inclusion criteria
1. Women aged 18-90 years with DCIS or Invasive Breast cancer containing DCIS diagnosed histopathologically
2. Histologically diagnosed DCIS or invasive lobular cancer in core biopsy (B5a or B5b). Invasive lobular carcinoma does not require concomitant DCIS.
3. Tumour size 1.5cm - 4cm and undergoing BCS
4. Written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
90 Years

Sex
Both

Target number of participants
Planned Sample Size: 460; UK Sample Size: 460

Total final enrolment
467

Key exclusion criteria
1. Unsuitable for BCS on basis of tumour size (>4cm) or stage.
2. Radiotherapy contraindicated.
3. No histopathological evidence of DCIS or invasive lobular cancer.
4. Small invasive cancers (<1.5cm)
5. Multicentric Disease (histologically diagnosed cancer in two different quadrants of the breast), unless resected in a single specimen
6. Bilateral disease (diagnosed cancer in both breasts)
7. Neoadjuvant systemic therapy
8. Previous radiation in the operated breast
9. Implants in the operated breast
10. Pregnancy
11. Lactation
12. Cryo-assisted localisation
13. Patients who are undergoing full cavity excision following removal of the main lumpectomy specimen during initial lumpectomy procedure.

Date of first enrolment
22/03/2016

Date of final enrolment

31/10/2017

Locations

Countries of recruitment
England

Scotland

United Kingdom

Study participating centre
Wythenshawe Hospital
University Hospital of South Manchester NHS Foundation Trust
The Nightingale Centre and Genesis Prevention Centre
Southmoor Road
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Study participating centre
St James's University Hospital
Leeds Teaching Hospitals NHS Trust
Bexley Wing,
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Study participating centre
Royal Derby Hospital
Derby Teaching Hospitals NHS Foundation Trust
Lymphoedema and Palliative Medicine
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Study participating centre
Addenbrookes Hospital
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NIHR CRN Eastern
Hills Road
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Study participating centre
Western General Hospital
NHS Lothian
Edinburgh Breast Unit
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Study participating centre
Macclesfield District General Hospital
Cancer Resource Centre
Victoria Road
Macclesfield
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SK10 3BL

Study participating centre
The Royal Bournemouth and Christchurch Hospitals
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00he80998

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal with intention to publish the findings from the trial approximately 1 year after trial closure.

Intention to publish date
30/09/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from nigel.bundred@manchester.ac.uk

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 3.3	11/01/2019	04/10/2022	No	No
HRA research summary			28/06/2023	No	No