ISRCTN10169595 https://doi.org/10.1186/ISRCTN10169595

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

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

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

Contact name
Miss Sarah Bowers

Contact details
Nightingale & Prevent Breast Cancer Centre
Wythenshawe Hospital
Southmoor Road
Wythenshawe
Manchester
United Kingdom
M23 9LT
+44 161 291 4408
sarah.bowers@mft.nhs.uk

Additional identifiers

ClinicalTrials.gov (NCT)
NCT02774785

Protocol serial number
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

Primary study design
Interventional

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

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
90 Years

Sex
All

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
United Kingdom

England

Scotland

Study participating centre

Wythenshawe Hospital
University Hospital of South Manchester NHS Foundation Trust
The Nightingale Centre and Genesis Prevention Centre
Southmoor Road
Wythenshawe
Manchester
United Kingdom
M23 9LT

Study participating centre
St James's University Hospital
Leeds Teaching Hospitals NHS Trust
Bexley Wing,
Beckett Street
Leeds
United Kingdom
LS9 7TF

Study participating centre
Royal Derby Hospital
Derby Teaching Hospitals NHS Foundation Trust
Lymphoedema and Palliative Medicine
M&G Level 3
Uttoxeter Road
Derby
United Kingdom
DE22 3NE

Study participating centre
Addenbrookes Hospital
Cambridge University Hospitals NHS Foundation Trust
NIHR CRN Eastern
Hills Road
Cambridge
United Kingdom
CB2 0QQ

Study participating centre
Western General Hospital
NHS Lothian
Edinburgh Breast Unit

Edinburgh
United Kingdom
EH4 2XU

Study participating centre
Macclesfield District General Hospital
Cancer Resource Centre
Victoria Road
Macclesfield
United Kingdom
SK10 3BL

Study participating centre
The Royal Bournemouth and Christchurch Hospitals
Castle Ln E
Bournemouth
United Kingdom
BH7 7DW

Sponsor information

Organisation
University Hospital of South Manchester

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

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?
HRA research summary			28/06/2023	No	No
Protocol file	version 3.3	11/01/2019	04/10/2022	No	No