

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

<b>Submission date</b> 20/02/2017	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 27/03/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 04/10/2022	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

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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  
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

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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](mailto: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?
<a href="#">Protocol file</a>	version 3.3	11/01/2019	04/10/2022	No	No
<a href="#">HRA research summary</a>			28/06/2023	No	No