

# National study examining the treatment and outcome of patients diagnosed with breast cancer recurrence within the same breast/chest wall/nearby lymph glands

<b>Submission date</b> 16/09/2021	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 25/11/2021	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 11/12/2023	<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-study-looking-at-the-management-of-breast-cancer-that-has-come-back-in-the-same-breast-or-nearby#undefined> (added 24/03/2022)

### Background and study aims

Although the 5-year UK breast cancer survival rate is favourable at 86.6%, patients continue to develop breast cancer recurrence within the same breast after breast-conserving surgery, as well as in the remaining skin or chest wall after mastectomy. Patients also present with breast cancer recurrence in the nearby lymph glands (under the arms or above/below the collarbone). These recurrences are collectively termed locoregional recurrence (LRR). It is estimated that up to 8% of breast cancer patients are diagnosed with LRR 10 years after their diagnosis. Currently there is a lack of high-quality data and clinical guidance for the optimal management of breast cancer patients diagnosed with LRR. In the UK, breast cancer recurrence is under-reported at the individual hospital level to the national cancer registries. As a result, analysis of existing routine data sources is unlikely to provide data on patient management that is reflective of current national practice.

The aim of this study is determine the frequency, current management and prognosis of patients diagnosed with breast cancer LRR with or without distant metastasis in the UK with the aim of establishing best practice and informing future national guidelines. Over 50 UK breast units will participate in the study.

### Who can participate?

Patients aged over 18 years treated for previous breast cancer

### What does the study involve?

The researchers will establish a national prospective cohort of patients newly diagnosed with LRR (with or without distant metastasis) and describe how these patients are managed, and examine any geographical variation in the care received. The participants will be followed up at

two timepoints (3 and 5 years) in order to determine patient survival outcome (breast cancer related or not), as well as the development of any further locoregional re-recurrence or distant metastasis. Patient survival analysis will identify prognostic factors, which will in turn generate hypotheses for future related studies with an aim of improving patient outcomes.

What are the possible benefits and risks of participating?

The researchers cannot promise that the study will benefit the study participant directly, but the information provided will help to improve the future management of patients diagnosed with breast cancer locoregional recurrence. There are no specific risks related to study participation. Taking part in this study will not change any treatment plans or investigations recommended by the medical team.

Where is the study run from?

Leeds Teaching Hospitals NHS Trust (UK)

When is the study starting and how long is it expected to run for?

September 2020 to January 2029

Who is funding the study?

Association of Breast Surgery (UK)

Who is the main contact?

Mr Baek Kim

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## Contact information

**Type(s)**

Scientific

**Contact name**

Mr Baek Kim

**ORCID ID**

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**Contact details**

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## Additional identifiers

**Clinical Trials Information System (CTIS)**

Nil known

## **Integrated Research Application System (IRAS)**

285389

## **ClinicalTrials.gov (NCT)**

Nil known

## **Protocol serial number**

CPMS 50013, ABSGrantMARECA2020, IRAS 285389

# **Study information**

## **Scientific Title**

The MARECA study - National study of management of breast cancer locoregional recurrence and oncological outcome

## **Acronym**

MARECA

## **Study objectives**

For patients diagnosed with breast cancer locoregional recurrence (LRR), there is clinical uncertainty with regards to what constitutes optimal patient management and if geographical variations exist in patient care. The key areas that require evaluation include radiological staging investigations and the proportion of patients found to have distant metastasis at presentation, surgical management including the use of repeat breast-conserving surgery and sentinel lymph node biopsy, and information about adjuvant treatment modalities used, as well as the patient's subsequent prognosis. Collection of these data will provide a national picture of patient management and enable the identification of clinicopathological factors that predict patient prognosis.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Approved 07/09/2021, London - Brighton & Sussex Research Ethics Committee (Health Research Authority, 2 Redman Place, E20 1JQ, UK; +44 (0) 207104 8202; brightonandsussex.rec@hra.nhs.uk), REC ref: 21/PR/1128

## **Study design**

Observational cohort study

## **Primary study design**

Observational

## **Study type(s)**

Other

## **Health condition(s) or problem(s) studied**

Breast cancer

## **Interventions**

This is a prospective, observational, multicentre, longitudinal cohort study. This will be a national collaborative research study delivered in collaboration with the Association of Breast Surgery (ABS) Academic and Research committee and the breast surgery and oncology trainee associations (the Mammary Fold and UK Breast Cancer Trainees Research Collaborative Group).

The study will have two main phases:

**National prospective cohort study:** In 2021, over 50 UK breast units will aim to recruit consecutive eligible patients newly diagnosed with locoregional recurrence (LRR) +/- distant metastasis. The study will recruit patients for 24 months. Eligible patients will be identified at the breast MDT meetings or in breast and oncology clinics. We anticipate each unit to recruit 5 to 10 patients per year. Therefore, the anticipated sample size is 500 patients.

All prospective consecutive patients will be approached and those that fulfil all the eligibility criteria will be given the Patient Information Sheet and given time to read the information and ask any questions about the study. Once the patient has had time to consider the information and ask questions, and if they choose to participate in the study, written informed consent will be obtained. Consent can be taken by the consultant breast surgeon or oncologist, breast surgery or oncology trainees, research nurses, or appropriately trained clinical trials assistants where delegated by the Chief/Principal Investigator. The patient consent will include the permission to collect pseudonymised data on the patient's initial and recurrent cancer treatment. This will include permission to examine the patient's survival and re-recurrence at 3 and 5 years after their LRR diagnosis.

Patients will also be provided with the option of consenting for permission to access archival tumour tissue or slides of the initial and recurrent breast cancer for potential future related tissue substudy. Patients can participate in the main study without consenting to tissue or slide access.

The participating patients will receive standard care and study participation will not result in additional tests, interventions, or clinic visits. Once patient consent has been obtained, consultant breast surgeon or oncologist, breast surgery or oncology trainees, research nurses, or clinical trials assistant will collect data detailing the tumour pathology, imaging results, surgical treatment, radiotherapy, and systemic therapy of initial and recurrent cancer for the study participant. These data are routinely collected as part of standard clinical practice. The study data will be recorded in a pseudonymised format using a secure web-based database (REDCap; hosted at the University of Manchester). This will enable the description of the current national practice including:

1. Modality of radiological staging investigations used and determination of the rate of detection of distant metastasis
2. Proportion of patients undergoing repeat breast-conserving surgery (BCS)
3. Proportion of patients undergoing repeat sentinel lymph node biopsy (SLNB), techniques used, and their success rate in terms of SLN identification
4. Adjuvant treatment modalities used to treat LRR
5. Proportion of patients undergoing breast surgery for LRR in the presence of distant metastasis

Separately, a local secure record will be kept of the RedCap ID with corresponding NHS number (in England and Wales), Community Health Index number (in Scotland), or Health and Care number (in Northern Ireland) for future identification of patients. This is required for the research team at each participating centres to access the hospital electronic system to determine the follow up oncological outcome data for the study participants.

Oncological outcome evaluation: At 3 and 5 year follow up after the LRR diagnosis, the research team at each participating unit (Consultant PI, research nurse, and clinical trial assistants) will also access the hospital electronic system to record survival and re-recurrence outcome for each study participants.

Statistical survival analysis will be performed to determine patient survival and re-recurrence rates for the study cohort. There are planned statistical analyses to determine potential predictive factors that influence patient survival. A power calculation has determined that a subset of 330 patients diagnosed with LRR (without associated distant metastasis at presentation) are required to determine the study's primary endpoint (disease-free survival following LRR resection, stratified according to the type of surgery performed for the initial breast cancer; BCS and radiotherapy vs mastectomy).

The researchers will not anticipate direct patient contact for the study purpose during this follow up period as all the required information should be available on the hospital electronic system. In cases where the required information is missing or unclear, the research team may contact the patient or their General Practitioner via telephone.

### **Intervention Type**

Other

### **Primary outcome(s)**

Disease-free survival following locoregional recurrence resection measured using patient records at 3 and 5 years follow up

### **Key secondary outcome(s)**

1. Progression-free survival in patients who present with breast cancer locoregional recurrence with distant metastasis (3 and 5 years follow up).
2. Overall survival in patients diagnosed with breast cancer locoregional recurrence +/- distant metastasis at presentation (3 and 5 years follow up)

### **Completion date**

30/01/2029

## **Eligibility**

### **Key inclusion criteria**

1. Female or male patients more than 18 years old
2. Treated for previous unilateral or bilateral breast cancer (invasive cancer including all histological subtypes as well as ductal carcinoma in situ) with curative intent
3. No previous evidence of distant metastatic disease
4. Recently (within the last 6 months) diagnosed with new ipsilateral locoregional recurrence (biopsy-proven invasive cancer including all histological subtypes or ductal carcinoma in situ) +/- distant metastasis
5. Able to provide written informed consent
6. A minimum of 3 months interval between the resection surgery for the original cancer and the diagnosis of locoregional recurrence. There will be no maximum interval time period

### **Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Patients where the new breast cancer diagnosis is in the contralateral breast
2. For patients who present with new bilateral breast cancer, the side with no previous cancer will be excluded
3. Patients diagnosed with distant metastatic disease with no evidence of locoregional recurrence
4. Patients diagnosed with angiosarcoma
5. Patients with previous history of non-breast cancer treatment that was non-curative in intent
6. Patients who have had previous ipsilateral surgery for atypia, benign conditions, or phyllodes tumour and other breast sarcomas
7. Patients under 18 years old
8. Patients lacking the capacity to provide written informed consent

**Date of first enrolment**

08/11/2021

**Date of final enrolment**

31/12/2023

**Locations****Countries of recruitment**

United Kingdom

England

Northern Ireland

Scotland

Wales

**Study participating centre**

**St. James's University Hospital**

Beckett Street

Leeds

United Kingdom  
LS9 7TF

**Study participating centre**  
**The Royal Marsden Hospital**  
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SW3 6JJ

**Study participating centre**  
**Southampton General Hospital**  
Tremona Road  
Southampton  
United Kingdom  
SO16 6YD

**Study participating centre**  
**Manchester Royal Infirmary**  
Oxford Road  
Manchester  
United Kingdom  
M13 9WL

**Study participating centre**  
**Southmead Hospital**  
Southmead Road  
Westbury-On-Trym  
Bristol  
United Kingdom  
BS10 5NB

**Study participating centre**  
**Doncaster Royal Infirmary**  
Armthorpe Road  
Doncaster  
United Kingdom  
DN2 5LT

**Study participating centre**  
**University College Hospital**  
250 Euston Road  
London  
United Kingdom  
NW1 2PG

**Study participating centre**  
**Belfast Health & Social Care Trust**  
Knockbracken Healthcare Park  
Saintfield Road  
Belfast  
United Kingdom  
BT8 8BH

**Study participating centre**  
**Bradford Royal Infirmary**  
Duckworth Lane  
Bradford  
United Kingdom  
BD9 6RJ

**Study participating centre**  
**Poole Hospital**  
Longfleet Road  
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United Kingdom  
BH15 2JB

**Study participating centre**  
**Freeman Hospital**  
Freeman Road  
High Heaton  
Newcastle upon Tyne  
United Kingdom  
NE7 7DN

**Study participating centre**  
**Harrogate District Hospital**  
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Harrogate

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HG2 7SX

**Study participating centre**  
**Hull Royal Infirmary**  
Anlaby Road  
Hull  
United Kingdom  
HU3 2JZ

**Study participating centre**  
**Ysbyty Gwynedd**  
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LL57 2PW

**Study participating centre**  
**NHS Forth Valley**  
33 Spittal Street  
Stirling  
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FK8 1DX

**Study participating centre**  
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United Kingdom  
ML3 0TA

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**NHS Fife**  
Springfield House  
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KY15 5UP

**Study participating centre**

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EX2 5DW

**Study participating centre**

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WF1 4DG

**Study participating centre**

**Milton Keynes University Hospital**

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**Study participating centre**

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United Kingdom  
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**Study participating centre**

**Huddersfield Royal Infirmary**

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HD3 3EA

**Study participating centre**

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S44 5BL

**Study participating centre**

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## Sponsor information

**Organisation**

Leeds Teaching Hospitals NHS Trust

**ROR**

<https://ror.org/00v4dac24>

## Funder(s)

**Funder type**

Other

**Funder Name**

Association of Breast Surgery

**Alternative Name(s)**

British Association of Surgical Oncology, ABS, BASO

**Funding Body Type**

Government organisation

## Funding Body Subtype

Associations and societies (private and public)

## Location

United Kingdom

# Results and Publications

## Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study will be included in the subsequent results publication.

## IPD sharing plan summary

Other

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Other publications</a>	National practice questionnaire of United Kingdom multi-disciplinary decision making	01/07/2022	17/11/2023	Yes	No
<a href="#">Participant information sheet</a>	version 3.0	29/08/2021	23/09/2021	No	Yes
<a href="#">Participant information sheet</a>	version 3.1	26/10/2022	11/12/2023	No	Yes
<a href="#">Protocol file</a>	version 3.0	29/08/2021	23/09/2021	No	No
<a href="#">Protocol file</a>	version 4.0	25/05/2022	11/12/2023	No	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes