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Identifying factors that predict the need for increased tissue removal during breast-conserving surgery for breast cancer, in order to reduce the need for a second surgery

Submission date
11/11/2019

Recruitment status
No longer recruiting

Registration date
21/11/2019

Overall study status
Completed

Last Edited
01/12/2022

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Breast cancer affects many women across the globe each year. If the cancer is detected at an early stage most of the patients can be treated with breast-conserving surgery. This means that the surgeon then aims to remove only the tumor-bearing part of the breast as opposed to the whole breast. Patients treated with radiotherapy after initial breast-conserving surgery have been shown to have similar survival rates to patients where the whole breast is taken away. As improved surgical techniques have evolved, more patients can be operated on using breast-conserving surgery. After breast-conserving surgery there is a risk that the cancer-affected area is not be completely removed and the patient might need to undergo surgery again. This study aims to identify those patients at increased risk of needing a second operation due to incomplete removal of breast cancer after their first breast-conserving operation. If there are risk factors identifiable before the first surgical procedure, doctors could select the right patients for breast-conserving surgery in the future and identify patients at risk of having incomplete operations. This would also be helpful for the surgeon to know when to remove a larger part of the breast during the operation.

Who can participate?
All female patients operated with breast-conserving surgery for pre-stages of breast cancer or breast cancer at Skåne University Hospital in Malmö, Sweden, during the years 2015-2016 will be included as study patients. For comparison, patients from Skåne University Hospital and Kristianstad Central Hospital in 2017 will be included.

What does the study involve?
This study will only examine the patients' medical records from the surgical, pathology, operational and mammography departments. Patient and tumor characteristics such as age, height, weight, breast size and tumor size, location and type will be recorded. Patients in need of second surgery will then be compared to patients with complete first operations in order to identify patient and tumor characteristics associated with incomplete removal of the tumor. All

data will be compiled with no identifying information and no new information about the patients will be gathered.

What are the possible benefits and risks of participating?
There are no direct physical risks to the participants because the study uses only their medical records. The risks of participating in our study is mainly the potential intrusion on privacy from having data extracted from personal medical records. This intrusion is limited by the ethic committee's decision to only allow access to the medical records from the surgical clinic and from the time of the events and by defining which data can be collected. The study aims is that all women affected by breast cancer in the future will be benefited by the knowledge gained on risk factors for having to have a second operation and the possibility of more patients being successfully treated with breast-conserving surgery and a single surgery.

Where is the study run from?
Lund University (Sweden)

When is the study starting and how long is it expected to run for?
January 2017 to December 2017

Who is funding the study?
Lund University (Sweden) and Region Skåne (Sweden)

Who is the main contact?
Dr Julia Ellbrant, Julia.Ellbrant@med.lu.se

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Pre-operative patient and tumor characteristics associated with increased risk of non-radical margins after breast-conserving surgery

Study objectives
Preoperative patient and tumor characteristics can be associated with non-radical margins after breast-conserving surgery and therefore be pre-operatively identified.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/01/2018, Regional Ethical Review Board in Lund, Sweden Etikprövningsnämden i Lund (Box 133, 22100, Lund, Sweden; +46 (0)104750800; registrator@etikprovning.se), Ref: Dnr 2018/622

Study design
Observational retrospective cross-sectional record review. Multicenter design with internal and external validation cohorts

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Diagnostic

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Breast cancer patients operated on using breast-conserving surgery

Interventions
All female patients operated with breast-conserving surgery for pre-stages of breast cancer or with breast cancer at Skåne University Hospital in Malmö, Sweden during the years 2015-2016 will be included as study patients. For comparison, patients from Malmö and Kristianstad Central

Hospital, Sweden, in 2017 will be included as a validation population. The patients' medical records from the surgical, pathology, operational and mammography departments are collected extracting pre-defined factors. Patient and tumor characteristics such as age, height, weight, breast size and tumor size, location and type will be recorded. Patients will be analysed divided into two groups, radical and not radical at first surgery. Patients in need of second surgery will then be compared to patients with complete first operations in search of patient and tumor characteristics associated with incomplete removal of the tumor. All data will be compiled de-identified and no new information about the patients are gathered other than existing information already known by the patients.

Intervention Type
Procedure/Surgery

Primary outcome measure
All measured retrospectively and extracted from medical records:
1. Number of patients with non-radical breast conserving surgery after first procedure
2. Preoperative tumor and patient characteristics such as age, BMI, breast side and size, screening detection, palpability of tumor, location in breast, distance from mamilla, lymph node palpability and status, previous breast operations, radiographic characteristics and size, biopsy results

Secondary outcome measures
All measured retrospectively and extracted from medical records:
Post-operative tumor and patient characteristics such as method of operation, indication method, pathology results from tumor and axilla, weight of excised lump and operation time

Overall study start date
01/01/2017

Completion date
30/12/2017

Eligibility

Key inclusion criteria
Female patients operated with breast-conserving surgery with a final diagnosis of in situ or invasive cancer at Skåne University Hospital 2015-2016 for study cohort or 2017 for validation cohort or at Kristianstad hospital in 2017 for external validation

Participant type(s)
Patient

Age group
All

Sex
Female

Target number of participants
779

Key exclusion criteria
1. Male gender
2. Primary operation not coded as breast-conserving surgery
3. Neoadjuvant treatment
4. Benign final pathology result

Date of first enrolment
01/01/2015

Date of final enrolment
31/12/2017

Locations

Countries of recruitment
Sweden

Study participating centre
Skåne University Hospital, Surgical clinic
Jan Waldenströmsgata 11 A
Malmö
Sweden
205 02

Study participating centre
Kristianstad Hospital, Surgical clinic
Jan Hedlundsväg 5
Kristianstad
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291 33

Sponsor information

Organisation
Lund University

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Sponsor type
University/education

Website
www.lu.se

ROR
https://ror.org/012a77v79

Funder(s)

Funder type
University/education

Funder Name
Lunds Universitet

Alternative Name(s)
Lund University, Universitas Lundensis, Universitas Gothorum Carolina, Royal Caroline Academy, Regia Academia Carolina, Lund University | Lund, Sweden | LU, Lunds universitet, LU

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Sweden

Funder Name
Region Skåne

Results and Publications

Publication and dissemination plan
Publication planned as original article in a peer-reviewed journal in 2020.

Intention to publish date
01/03/2020

Individual participant data (IPD) sharing plan

The exact data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results	Presented at 2018 San Antonio Breast Cancer Symposium	01/02/2019	03/09/2021	No	No
Results article		06/09/2021	01/12/2022	Yes	No