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Cosmetic results for patients with breast cancer operated with bilateral reduction mammoplasty

Submission date
10/10/2019

Recruitment status
No longer recruiting

Registration date
08/11/2019

Overall study status
Completed

Last Edited
05/02/2021

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 thousands of women in Sweden every year and is the most common type of cancer in women. In the year 2016 as many as 7500 women in Sweden were diagnosed with breast cancer. Using oncoplastic techniques in breast cancer surgery allows for a generous resection of breast tissue and therefore a reduction in non-radical surgery and studies has also shown that patients are more satisfied with the cosmetic outcome. The use of breast-reduction techniques is one of the most commonly used in oncoplastic breast surgery. Bilateral breast reduction in combination with breast-cancer surgery (therapeutic mammoplasty) has the benefit of reducing the volume of the breasts as well as assuring good symmetry after surgery. In patients with breast cancer combined with mammary hyperplasia and a good health status it is a valuable option to consider, even with smaller tumours. The INESC porto research group has created software called Breast Cancer Conservative Treatment cosmetic results (BCCT.core) which assesses photographs and produces a rated result: poor, fair, good or excellent aesthetic outcome. The evaluation is based on symmetry, skin colour and scar appearance. The main study aim is to assess the cosmetic outcome, evaluated by BCCT.core, at the time of breast cancer diagnosis, after bilateral therapeutic mammoplasty and at 1-year follow-up.

Who can participate?
Patients who underwent bilateral therapeutic mammoplasty between 2011 and August 2018 (data collected from digital patient records)

What does the study involve?
For the postoperative photos information is extracted from BCCT.core including the 4-grade cosmetic outcome and a value for symmetry between the breasts. For the preoperative photos BCCT.core is used only to extract the symmetry score, since BCCT.core is designed for evaluating the cosmetic outcome for postoperative photos. Values on a 10-grade scale for cosmetic outcomes are recorded for both patient and surgeon on 1-year follow-up. The surgeon's and patient's grading of cosmetic outcome is made primarily on the 1-year follow-up, with a few exceptions where it is done in retrospect by the surgeon based on the postoperative photos.

What are the possible benefits and risks of participating?
The possible benefits are that it can lead to a better understanding of the cosmetic outcomes

for patient undergoing this type of surgery, so surgeons in the future can make the best possible choices regarding surgery for breast cancer patients. There are no potential risks for the patients involved since this is a register study only, also all the patients have been de-identified in the dataset. There was also an opt-out option available for the potential patients in the study, in form of an article in the local newspaper calling on patients who fulfilled the inclusion criteria to contact the responsible party if they did not wish to participate.

Where is the study run from?
Kirurgen, Centralsjukhuset Kristianstad (Sweden)

When is the study starting and how long is it expected to run for?
October 2018 to October 2019

Who is funding the study?
1. Lunds Universitet (Sweden)
2. Region Skåne (Sweden)

Who is the main contact?
Dr Kim Gulis
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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
Cosmetic outcome and symmetry for patients who have undergone bilateral therapeutic mammoplasty for breast cancer

Study objectives
To evaluate the cosmetic outcome after bilateral therapeutic mammoplasty.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 04/12/2018, Etikprövningsnämnden i Lund (Box 133, 22100, Lund, Sweden; Tel: +46 (0) 104750800; Email: registrator@etikprovning.se), Dnr 2018/827

Study design
Retrospective observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet

Health condition(s) or problem(s) studied
Cosmetic outcome after breast cancer surgery

Interventions
The patients eligible for inclusion is all patients operated with bilateral therapeutic mammoplasty between 2011 and until August 2018, the patients were identified and the data was retrospectively collected from digital patient records.

Regarding the aesthetic outcome from a more impartial view, INESC porto research group has created an objective software called the Breast Cancer Conservative Treatment cosmetic results (BCCT.core). This software assesses photographs and produces a rated result: poor, fair, good or excellent aesthetic outcome. The evaluation is based on symmetry, skin colour and scar appearance.

For the postoperative photos, information is extracted from BCCT.core including the 4-grade cosmetic outcome and a value for symmetry between the breasts. For the preoperative photos, BCCT.core is used only to extract the symmetry score, since BCCT.core is designed for evaluating the cosmetic outcome for postoperative photos. Values on a 10-grade scale for cosmetic outcomes have been registered for both patient and surgeon on 1-year follow-up. The surgeons and patients grading of cosmetic outcome was made primarily on the 1-year follow-up, with few exceptions where it was done in retrospect by the surgeon based on the postoperative photos.

Intervention Type
Other

Primary outcome measure
1. Cosmetic outcome measured using BCCT.core score on a 4-grade scale 1-year postoperatively
2. Symmetry measurements from BCCT.core preoperative and 1-year postoperative
3. Patient's cosmetic scores on a scale of 1-10 at 1-year postoperatively
4. Surgeon's cosmetic scores on a scale of 1-10 at 1-year postoperatively

Secondary outcome measures
1. Complications documented for each breast separately according to Clavien-Dindo classification 2 weeks postoperatively and 1 year postoperatively
2. Breast size in ml measured using plastic breast cups preoperatively
3. Breast measurements in cm measured using measuring tape preoperatively
4. Percentage of breast excised during surgery measured by dividing the weight of the breast tissue excised in surgery with the weight of the breast
5. Axillary dissection in surgery, measured by if there was an axillary clearance or not
6. Tumor characteristics in pathology answers measured using pathology reports 2 weeks postoperatively

Overall study start date
01/10/2018

Completion date
01/10/2019

Eligibility

Key inclusion criteria
All patients operated with bilateral therapeutic mammoplasty between 2011 and August 2018 in Centralsjukhuset Kristianstad

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex

Female

Target number of participants
150

Total final enrolment
146

Key exclusion criteria
1. Patients who had a mastectomy before the 1-year postoperative follow-up
2. Patients who had a nipple removed during the surgery due to tumor location
3. Patients where the postoperative 1-year photos were missing
4. Patients who died before the 1-year follow-up

Date of first enrolment
01/10/2018

Date of final enrolment
01/10/2019

Locations

Countries of recruitment
Sweden

Study participating centre
Kirurgen, Centralsjukhuset Kristianstad
J A Hedlundsväg 5
Kristianstad
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29133

Sponsor information

Organisation
Region Skåne

Sponsor details
Centralsjukhuset Kristianstad
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/03sawy356

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 2020. There are to date no publications or additional documents available online.

Intention to publish date
01/10/2020

Individual participant data (IPD) sharing plan
The 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?
Results article	results	01/05/2021	05/02/2021	Yes	No