

The impact of shoulder complaints and anxiety on quality of life in breast cancer patients.

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Investigate the consequences of axillary lymph node dissection (ALND) and sentinel lymph node procedure (SNP) regarding shoulder impairments, the activities a women still undertakes and the role of quality of life and anxiety in this in women who...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Breast neoplasms malignant and unspecified (incl nipple)
Study type	Observational non invasive

Summary

ID

NL-OMON32560

Source

ToetsingOnline

Brief title

Shoulder complaints breast cancer patients

Condition

- Breast neoplasms malignant and unspecified (incl nipple)
- Breast therapeutic procedures

Synonym

breast cancer

Research involving

Human

Sponsors and support

Primary sponsor: Sint Elisabeth Ziekenhuis

Source(s) of monetary or material Support: gefaciliteerd door St. Elisabeth ziekenhuis

Intervention

Keyword: anxiety, breast cancer, quality of life, shoulder impairments

Outcome measures

Primary outcome

- type of surgery
- physical complaints: pain, lymph edema, loss of strength, limitations (in daily life)
- shoulder impairments (abduction, endo/exorotation, ventral/dorsal elevation) and arm circumference
- quality of life, health status
- state anxiety and trait anxiety

Secondary outcome

- number of surgeries
- tumor localization/side/size
- number of positive lymph nodes
- complications after surgery
- adjuvant treatment
- medication

Study description

Background summary

Breast cancer is the most common form of cancer in women. There are two types of surgery: breast conserving therapy and mastectomy. Also the axillary lymph nodes will be examined (sentinel lymph node procedure, SNP). When these nodes contain tumor cells, an axillary lymph node dissection (ALND) will be

performed. This procedure is preferred in early stage breast cancer, because often there are no metastasis and it is associated with a faster recovery and a shorter hospital stay than the ALND. Besides, an ALND can be first choice (especially when there are suspicious palpable axillary lymph nodes), in which all axillary lymph nodes will be removed. Both procedures can lead to range of motion limitations in the arm. Patients who underwent an ALND, often have more pain, experience more sensory disorders, have more often lymph edema, have limitations of shoulder function and experience less strength at the operated side. With regard to the health status, women with ALND have more limitations in daily life and, within one year after surgery, they have less improvement of function than the patients who only underwent SNP. Recently, a randomized multi center trial found that SNP is preferred over ALND in women with early stage breast cancer, because of the decreased arm morbidity and a better quality of life after 12 months of follow-up. At the same time physiotherapy after ALND has a favorable effect on shoulder and arm complaints and on quality of life compared to conservative treatment (explanation and advice). However, it is unknown which limitations women rightly or wrongly lay upon themselves in doing all sorts of activities. Furthermore, there is little known about the long term consequences of both procedures.

Study objective

Investigate the consequences of axillary lymph node dissection (ALND) and sentinel lymph node procedure (SNP) regarding shoulder impairments, the activities a women still undertakes and the role of quality of life and anxiety in this in women who had an SNP and/or ALND at least 6 months till almost 7 years ago. Also, investigate whether some patients may need extra counseling and information to better deal with their disease.

Study design

clinical, involving patients

Study burden and risks

- one visit to the investigator (length 45 minutes)
- filling in four or five questionnaires (quality of life, health status, measuring anxiety, physical complaints)
- physical examination: measuring function of both shoulder-joints, measuring arm circumference

Contacts

Public

Sint Elisabeth Ziekenhuis

Lange Nieuwstraat 191-32

5041 DB

Nederland

Scientific

Sint Elisabeth Ziekenhuis

Lange Nieuwstraat 191-32

5041 DB

Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- All women from January 2002 till May 2008 in St. Elisabeth Hospital (Tilburg, Netherlands) diagnosed with early stage breast cancer who underwent axillary lymph node dissection, sentinel lymph node procedure or both.

Exclusion criteria

- loco-regional recurrence or metastasis
- cognitive impairment
- doesn't speak Dutch
- shoulder impairments, not as a consequence of breast cancer

Study design

Design

Study type: Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 03-11-2008

Enrollment: 100

Type: Actual

Ethics review

Approved WMO

Date: 17-09-2008

Application type: First submission

Review commission: METC Brabant (Tilburg)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL24275.008.08