Ultrasound-guided breast-conserving surgery.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23565

Source
NTR

Brief title
COBALT trial

Health condition

Breast cancer, breast-conserving surgery, palpable, intra-operative ultrasonography, excision volume, cosmetic outcome, margin status, quality of life

Borstkanker, mammasparende chirurgie, palpabel ammacarcinoom, intra-operatieve echografie, excisievolume, cosmetiek, radicaliteit, kwaliteit van leven

Sponsors and support

Primary sponsor: VU University Medical Center
Dept. of Surgical Oncology
Prof.dr. J. bonjer, prof.dr. S. Meijer
De Boelelaan 1117
1081 HV Amsterdam
Source(s) of monetary or material Support: Stichting Pink Ribbon
The Dutch Pink Ribbon breast cancer foundation

Intervention

Outcome measures

Primary outcome

1. Excision volume;

2. Margin status.

Secondary outcome

1. Cosmetic outcome;

2. Quality of life.

Study description

Background summary

Breast-conserving therapy (BCT) for breast cancer is initiated as a method to preserve healthy breast tissue, thereby improving cosmetic outcomes. The cosmetic outcome after breast cancer surgery is an important determinant of patient satisfaction, maintenance of self-image and quality of life. Thus far, the primary aim of BCT has been focused on achieving tumour-free resection margins and preventing local recurrence, while the cosmetic outcome has been considered less important. Large studies have reported poor cosmetic outcomes in 20-40% of patients after BCT, and the volume of resected breast tissue is the major determinant of the cosmetic outcome. In daily practice, surgical resection of palpable breast cancer is performed with guidance by intra-operative palpation. Concerns about tumour involvement of resection margins, however, often result in unnecessarily wide resection of adjacent healthy breast tissue. Our recent large multicentre retrospective study showed that in 32% (112/351) of patients over 200% excessive healthy breast tissue was excised with the malignant tissue! The mean volume excessively excised was 142 cm^3 (64-423 cm^3; sd 86)! There is clear evidence for the efficacy of ultrasonography (US) in the resection of nonpalpable tumours, and US is an easy available and feasible method for continuous visualisation during surgery. Intra-operative US reduces the resection of healthy breast tissue and improves tumour-free resection margins. In the present study, the value of the use of US during the resection of palpable tumours of the breast will be investigated. The objectives will be to determine whether US-guided resection of palpable breast cancer allows sparing of the breast tissue while preserving tumour-free resection margins with improvements in cosmetic outcomes and quality of life.

Study objective

It is hypothesised that the use of intra-operative ultrasonography in the excision of palpable

breast cancer compared with the standard palpation-guided surgery will improve the ability to spare healthy breast tissue while maintaining or even improving the oncological margin status.

Study design

The inclusion period will run from October 2010 to July 2011.

The EORTC QLQ-C30/-BR23 questionnaire will be completed by the patient prior to surgery. Surgery will be scheduled 1-2 weeks after diagnosis.

During a follow-up visit to the outpatient clinic, usually 1-2 weeks after discharge, complications will be recorded and treated.

Three and six months after surgery, information will be collected from each patient concerning the cosmetic outcome and quality of life, and photographs will be taken.

Patients can withdraw from the study at any time during the study period.

Intervention

The use of intra-operative ultrasonography in the breast-conserving surgery for palpable breast cancer.

Control: The standard palpation-guided breast-conserving surgery (no use of intra-operative visualisation).

Contacts

Public
VU University Medical Center
De Boelelaan 1117
Nicole M.A. Krekel
Amsterdam 1081 HV
The Netherlands
+31 (0)20 4440829
Scientific
VU University Medical Center
De Boelelaan 1117
Nicole M.A. Krekel
Amsterdam 1081 HV
The Netherlands

+31 (0)20 4440829

Eligibility criteria

Inclusion criteria

1. Women age 25-75 yrs who are diagnosed with palpable early-stage (T1-2N0-1) primary breast cancer in the trial centres. Breast cancer will be diagnosed with physical examination, mammography (2R) and US of the breast and axilla. The diagnosis of invasive (ductal or lobular) breast cancer will be established with image-guided core needle biopsy or cytological puncture;

2. All patients will be suitable for BCT according to national guidelines;

3. Participants will not have a history of prior mammary surgery in the affected breast, radiation therapy or neo-adjuvant therapy;

4. Participants will have ASA Classification I – III;

5. Participants will be well-informed having signed an informed consent form.

Exclusion criteria

1. Participants with a history of prior mamma surgery, radiation therapy or neo-adjuvant therapy;

2. Patients younger than 25 years;

3. Patients age above 75 years.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2010
Enrollment:	120
Type:	Anticipated

Ethics review

Positive opinion

Date:	28-10-2010
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 36758
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL2463
NTR-old	NTR2579
CCMO	NL31664.029.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON36758

Study results

Summary results
N/A