Ultrasound-guided breast-conserving surgery.

Gepubliceerd: 28-10-2010 Laatst bijgewerkt: 15-05-2024

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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23565

Bron
Nationaal Trial Register

Verkorte titel
COBALT trial

Aandoening

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

Ondersteuning

Primaire sponsor: VU University Medical Center
Dept. of Surgical Oncology
Prof.dr. J. bonjer, prof.dr. S. Meijer
De Boelelaan 1117
1081 HV Amsterdam
Overige ondersteuning: Stichting Pink Ribbon
The Dutch Pink Ribbon breast cancer foundation

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Excision volume;
2. Margin status.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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).

Contactpersonen

Publiek

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

Wetenschappelijk

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

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind

Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-10-2010
Aantal proefpersonen:	120
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	28-10-2010
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 36758
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A