Three-Dimensional Ultrasound Volume Ratio for Improving Cosmetic Results in Breast Cancer Patients; TURACOS trial

Published: 11-11-2013
Last updated: 24-04-2024

The value of implementation and cost-efficacy of Tumor Volume / Breast Volume Ratio, as measured by Automated Breast Volume Scanner (ABVS), during the preoperative workup in breast cancer patients on 1) cosmetic result after BCS, and 2) surgical...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Breast neoplasms malignant and unspecified (incl nipple)
Study type	Interventional

Summary

ID

NL-OMON47039

Source
ToetsingOnline

Brief title
TURACOS trial

Condition

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

Synonym
breast cancer, Breast carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W,Nog geen geld

ontvangen;maar een aanvraag ligt bij Achmea

Intervention

Keyword: Breast cancer, Breast conserving surgery, Cosmetic result, Three-dimensional ultrasound

Outcome measures

Primary outcome

Primary outcome is cosmetic result as assessed by an independent panel.

Secondary outcome

Second outcomes are:

1) cosmetic result as assessed by the patient herself,

2) cosmetic result as assessed by an objective asymmetry measurement,

3) surgical technique performed,

4) pathological result (radicality and quantitative specimen volume),

5) patient satisfaction and,

6) quality of life, and

7) cost efficacy regarding less irradicality.

Study description

Background summary

The expected cosmetic result plays an important role in the decision between mastectomy and breast conserving surgery (possibly in combination with plastic surgical reconstructive techniques) in breast cancer patients. Moreover, cosmetic results influenes patient satisfactior and quality of life. Therefore, it is important to pay attention to the cosmetic result without having to make concessions on the oncological result. Still, on average 15% of the breast conserving surgeries (BCS) are irradical and reoperation is needed. Therefore, in current practice the result of BCS is not always satisfying for patient and medical proffesional. To be able to anticipate on inferior cosmetic result, the

surgeon needs a tool to predict the cosmetic result. This would make it possible to adequately inform the patient, aid in treatment decision making and create realistic expectations which result in potentially more patient satisfaction and quality of life. We have performed a retrospective study to volume measurements of tumor in relation to the breast and it's influence on cosmetic result after BCS. It showed that a larger Tumor Volume / Breast Volume (Volume Ratio) resulted in 1) worse cosmetic result, 2) less patient satisfaction, and 3) more irradicality. Consequently, we decided to study this volume ratio as part of preoperative workup, which has never been done before.

Study objective

The value of implementation and cost-efficacy of Tumor Volume / Breast Volume Ratio, as measured by Automated Breast Volume Scanner (ABVS), during the preoperative workup in breast cancer patients on 1) cosmetic result after BCS, and 2) surgical procedure performed, pathological result, patient satisfaction and quality of life.

Study design

The study desgin is an open, randomized and controlled clinical trial. Patients in the control group will receive standard peroperative workup with an additional ABVS Volume Ratio. The Volume Ratio will be blinded for alle participants and by that will not influence treatment decision making. The Volume Ratio in the intervention group will be inserted in the predicition model. The prediction will be encounted for the treatment decision making by multidiciplinary consultation and influence treatment advice given.

Intervention

All patients will undergo the Automated Breast Volume Scanner (ABVS) at the department of radiology, Erasmus MC Cancer Institute. Tumor Volume and Breast Volume will be measured and a Volume Ratio will be calculated as following: Tumor Volume / Breast Volume Ratio * 1000. Both patients in the control- and intervention arm receive standard preoperative workup which includes the multidisciplinary preoperative consultation who devises a treatment plan. If chosen for BCS, there is the possibility of doing a combined oncological- and plastic surgical procedure (oncoplastic surgery) with breast lift- and breast reduction techniques. For patients in the intervention arm, their Volume Ratio will be taken into consideration by devising the treatment plan advice. The advice is given to the patient by the treating surgeon, but the final treatment decision is made by patients. Both patients in the control- and intervention arm will receive three questionnaires preoperatively; 1) EORTC/EQ-5D-5L quality of life questionnaires, and 2) about the expectations regarding cosmetic result (BREAST-Q). Pre- and postoperatively (1 and 3 year after initial operation) the professional medical photographer will take three pictures of the breast

(between collar bone and umbilicus). Postoperative photos will be used for panel and assymetry evaluations. At a follow-up visit again three questionnaires are supposed to be filled in: 1) EORTC/EQ-5D-5L quality of life questionnaires and 2) concercing cosmetic result (BREAST-Q).

Study burden and risks

Minor risks are associated to participation in this study. Minimal burden to the patient is caused by 1) undergoing the Automated Breast Volume Scanner (ABVS) for 10 minutes, 2) visit to the medical photographer for 5 minutes, and 3) answering three questionnaires five times; two concering quality of life questionnaires (EORTC/EQ-5D-5L) and one concerning cosmesis (BREAST-Q), which takes 15 minutes in total. Almost all (if not all) interventions will be planned immediately following other visits at the Erasmus MC Cancer Institute. The EORTC/EQ-5D-5L quality of life questionnaire is extensively validated and the questionnaire concering cosmesis has been used by us in previous studies and has not been found burdensome to the patients. Attached to the questionnaires, contact information for the psychosocial support team will be given who can be contacted any time the patient feels uncomfortable with the questions asked and feels she wants to talk about it.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Female breast cancer patients
- Breast conserving surgery is optional and taken into consideration
- Lesion visible at ultrasound

Exclusion criteria

- Local recurrence of breast cancer
- Contraindication for combined oncological and reconstructive surgery

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-10-2015
Enrollment:	300
Type:	Actual

Medical products/devices used

Generic name:	Automated Breast Volume Scanner
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	11-11-2013
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	13-06-2014
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	09-06-2015
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	17-12-2015
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	31-08-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	14-03-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL44554.078.13