# TUmour-volume to breast-volume RAtio for Improving COSmetic Results in Breast Cancer Patients (TURACOS); a randomised controlled trial.

Gepubliceerd: 17-02-2015 Laatst bijgewerkt: 13-12-2022

Preoperative use of a prediction model in breast cancer patients, concerning tumour volume versus breast volume ratio and tumour localisation, improves cosmetic results in breast conserving surgery

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

## Samenvatting

### ID

NL-OMON21871

**Bron**
NTR

**Verkorte titel**
TURACOS

**Aandoening**

Breast conserving surgery, breast cancer, Quality of Life

### Ondersteuning

**Primaire sponsor:** C. Verhoef, Head of department & Surgeon
Department of Oncological Surgery
Erasmus MC-Daniel den Hoed
010-7041506
**Overige ondersteuning:** 1.Stichting Theia onderdeel van Zilveren Kruis Achmea
2.PEM; Speur- En ontwikkelingswerk op het gebied van gezondheid en voeding (niet biotechnologisch)
3.Stichting Coolsingel

## Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

Cosmetic outcome assessed through an independent panel.

# Toelichting onderzoek

### Achtergrond van het onderzoek

Long-term survival, recurrence rates and cosmetic result are important endpoints after breast conserving surgery (BCS) in breast cancer patients. Previous studies show that breast conserving surgery followed by radiation therapy is as safe, considering long-term survival and local recurrence rates, as mastectomy in breast cancer patients. Preoperative tools to predict good cosmetic outcome are not yet well established. We proved that tumour location and tumour volume versus breast volume ratio are independent predictors of a good cosmetic result when opting for breast conserving surgery. A prediction model based on these independent predictors and the quality of life in breast cancer patients followed by either breast conserving surgery or mastectomy (with or without direct reconstruction) will be tested in this study. Patients will randomly be assigned to either the intervention or the control group. All participants will undergo a preoperative three-dimensional ultrasonography to assess tumour- and breast-volume. In the intervention group the tumour volume and breast volume will be used for the prediction model. In the control group the three-dimensional ultrasonography will be calculated after inclusion of all participants. Taken the results of the prediction model in account a final decision will be made between breast conserving surgery or mastectomy (followed by direct reconstruction), aiming for the best cosmetic result.
An expert panel will, based on medical photographs, assess cosmetic outcome after BCS, primary outcome of the study. Secondary outcomes Quality of Life and psychosocial functioning will be measured with the EORTC and BREAST-Q questionnaire respectively. Other secondary outcome parameters concern pathological results, cost-effectiveness, radiation effects and cosmetic outcome as assessed by the BCCT.core software program. Patients' last follow up within the study will be 3 years after initial surgery. In summary, this study aims to improve cosmetic outcome following BCS in breast cancer patients by using a preoperative prediction model. By improving cosmetic outcome following BCS it is targeted to increase quality of life and psychosocial functioning in breast cancer patients.

### Doel van het onderzoek

Preoperative use of a prediction model in breast cancer patients, concerning tumour volume versus breast volume ratio and tumour localisation, improves cosmetic results in breast

conserving surgery

**Onderzoeksopzet**

Inclusion

Randomisation

Follow up T0 - prior to surgery

Follow up T1 - 2 weeks after initial surgery

Follow up T2 - 3 months after initial surgery

Follow up T3 - 1 year after initial surgery

Follow up T4 - 3 year after initial surgery/end of study

**Onderzoeksproduct en/of interventie**

Performing a three-dimensional ultrasonography to measure tumour volume and breast volume. The volume ratio will be translated using a prediction model aiming for superior cosmetic results in breast cancer patients opting for breast conserving surgery.

# Contactpersonen

## Publiek

Department of Surgery, Erasmus MC Cancer Institute
PO Box 5201
L.B. Koppert,
Secretary Department of Oncological Surgery, DHA-102,

Rotterdam 3008 AE
The Netherlands
(010-70)41161

## Wetenschappelijk

Department of Surgery, Erasmus MC Cancer Institute
PO Box 5201
L.B. Koppert,
Secretary Department of Oncological Surgery, DHA-102,

Rotterdam 3008 AE
The Netherlands
(010-70)41161

# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Female

Primary breast cancer

Pathologically proven breast cancer stage I-III

Aged > 18 years

Eligible for breast conserving surgery (BCS)

## Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Recurrent breast cancer ipsilateral

Previous radiation therapy ipsilateral breast

# Onderzoeksopzet

## Opzet

| | |
|---|---|
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Parallel |
| Toewijzing: | Gerandomiseerd |
| Blindering: | Open / niet geblindeerd |
| Controle: | N.v.t. / onbekend |

## Deelname

Nederland

| | |
|---|---|
| Status: | Werving gestart |
| (Verwachte) startdatum: | 01-09-2015 |
| Aantal proefpersonen: | 240 |
| Type: | Verwachte startdatum |

# Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 17-02-2015 |
| Soort: | Eerste indiening |

# Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

| Register | ID |
|---|---|
| NTR-new | NL4743 |
| NTR-old | NTR4997 |
| Ander register | NL44554.078.13 : MEC-2013-360 |

# Resultaten

**Samenvatting resultaten**

Vos EL, Koning AHJ, Obdeijn I-M, van Verschuer VMT, Verhoef C, van der Spek PJ, Menke-

Pluijmers MB, Koppert LB. Preoperative prediction of cosmetic results in breast conserving surgery. J Surg Oncol. 2014:n/a-n/a.