Towards omitting breast cancer surgery in patients without residual tumor after upfront chemotherapy.

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We hypothesize that in breast cancer patients with radiologic complete response (rCR) on MRI after primary systemic treatment (PST), a pathologic complete response (pCR) can reliably be predicted with use of multiple biopsies after PST.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON24346

Bron
NTR

Verkorte titel
MICRA

Aandoening

English: breast cancer, neoadjuvant systemic therapy, primary systemic treatment, MRI, pathologic complete response, biopsy, response assessment

Dutch: mammacarcinoom, neoadjuvante systemische therapie, neoadjuvante chemotherapie, MRI, pathologisch complete respons, biopt, responsevaluatie

Ondersteuning

Primaire sponsor: Netherlands Cancer Institute
Isala Hospital
University Medical Center Utrecht
(more centers will join)
Overige ondersteuning: Pink Ribbon

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To assess the value of multiple biopsies of the breast in determining pathologic response to primary systemic treatment. We will therefore calculate the sensitivity, specificity, positive predictive value and negative predictive value of post-PST biopsies of the breast.

Toelichting onderzoek

Achtergrond van het onderzoek

Improvements in PST for breast cancer patients have led to increasing rates of pCR. However, until now no imaging modalities (or techniques) have been described to reliably identify patients with a pCR of the breast. Therefore, many patients still encounter overtreatment since patients undergo surgery of the original tumour area to confirm the absence or presence of pCR after PST.

The ultimate aim of our study is to eliminate surgical treatment in breast cancer patients achieving pCR after PST, thus preventing overtreatment and improving quality of life. We will achieve this aim by identifying patients with pCR following PST without surgical removal of (part of the) breast.
We will assess the value of biopsies of the breast in determining pathologic response to PST, in patients with rCR on MRI.

The MICRA trial is a 3 year observational prospective cohort study. Patients included are patients who are diagnosed with invasive breast cancer and showed rCR on MRI after PST. In these patients, eight ultrasound-guided core biopsies (14G needle) are performed at the site of the original tumour bed, which is marked with before PST (with a iodine seed, clip or hydro marker). Immediately hereafter, breast surgery is performed. Pathology results of biopsies and surgical specimens are compared, to determine the accuracy of this diagnostic procedure. Results from these biopsies will be combined with data on imaging, patient and tumour characteristics.

For treatment of the breast these results will define 2 patient groups:

- Presence of residual disease can be reliably predicted on MRI without obtaining post-PST pathology

- Presence/absence of pCR needs to be assessed by biopsies, and surgery may be omitted if biopsies show no residual tumour

Doel van het onderzoek

We hypothesize that in breast cancer patients with radiologic complete response (rCR) on MRI after primary systemic treatment (PST), a pathologic complete response (pCR) can reliably be predicted with use of multiple biopsies after PST.

Onderzoeksopzet

4-2016: MEC approval

4-2016: Start patient accrual

12-2016: Submit pilot and study design for publication

4-2017: Start designing national registration study

12-2017: Interim analysis and report

4-2019: Finish patient accrual

4-2019: Submit study results for publication

Onderzoeksproduct en/of interventie

In all patients receiving PST, a marker is placed at the center of the tumor area before the start of PST. Adequate position of the marker is confirmed by mammography and/or ultrasound.
After completion of PST, a MRI is performed to evaluate radiologic response. In patients with a radiologic complete response, eight biopsies of the original tumor bed are obtained, just before surgery when patients are under general anaesthesia (to minimize patient discomfort). The biopsies are obtained with use of a 14-gauge core needle. Four biopsies are obtained at <0.5 cm distance of the marker and 4 biopsies are obtained at 1.0-1.5 cm distance of the marker. Immediately after collection of the biopsies, conventional surgery is performed, which may consist of breast conserving surgery or mastectomy.
Pathology results of the biopsies and resected specimens are compared, to assess whether pCR can be reliably determined on post-PST biopsies.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Age > 18 year

- Carcinoma of the breast

- Treatment with primary systemic treatment

- Tumour histology and receptor status established by pre-treatment core biopsy

- Suitable for response evaluation with MRI

- MRI scan after neoadjuvant systemic treatment showed complete radiologic response

- Placement of marker (clip, hydro marker, iodine seed) at the center of the original tumour bed

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Contra-indications for MR imaging

- Ductal carcinoma in situ associated with microcalcifications as shown by core biopsy

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	05-04-2016
Aantal proefpersonen:	440
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	02-11-2016
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	NL5939
NTR-old	NTR6120
Ander register	: N16MIC (local study ID number)

Resultaten