MICRA study: Minimally Invasive Complete Response Assessment of the breast after neoadjuvant systemic therapy

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Breast therapeutic procedures
Study type	Observational invasive

Summary

ID

NL-OMON47839

Source
ToetsingOnline

Brief title
MICRA trial

Condition

- Breast therapeutic procedures

Synonym
Breast cancer, breast tumour

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis

Source(s) of monetary or material Support: Pink Ribbon Nederland;Innovatiefonds Zorgverzekeraars

Intervention

Keyword: biopsy, breast, neoadjuvant chemotherapy, pathological complete response

Outcome measures

Primary outcome

The main endpoint is specificity of post-NST biopsies of the breast in assessing the presence of pCR after NST. Secondary endpoints are the false-negative rate, negative and positive predictive value and sensitivity of the biopsies.

Secondary outcome

- A secondary endpoint is to identify patient groups in which presence or absence of a pathologic complete response can be reliably predicted following neoadjuvant chemotherapy by imaging methods and/or post-NAC biopsies.

- Another secondary endpoint is to evaluate how many biopsies would be required to correctly assess the presence of a pathologic complete response.

Study description

Background summary

Over 60% of the women who are diagnosed with breast cancer in the Netherlands are treated with chemotherapy, which may be administered before (neoadjuvant chemotherapy or NAC) or after (adjuvant) locoregional treatment. Depending on the subtype, 10-75% of patients will have a pathologic complete response (pCR) after NAC. In this target group, surgery of the breast could be omitted, if post-NAC-biopsies, combined with data on imaging and pathology, can reliably predict a pCR. Consequently, overtreatment of the breast is prevented and

morbidity is minimized.

Study objective

To assess whether core biopsies of the breast after neoadjuvant chemotherapy can reliably predict a pathologic complete response. We will therefore calculate the sensitivity, specificity, positive predictive value and negative predictive value of post-NAC biopsies of the breast in assessing the presence of a pCR.
We aim to develop a decision tree to guide clinical decisions on local treatment in breast cancer patients treated with NAC.
For treatment of the breast this decision tree will define two patient groups:
- Presence or residual disease (no-pCR) can be reliably predicted without performing core biopsies and conventional breast surgery is indicated
- Presence of pCR needs to be assesses by core biopsies, and surgery may be omitted if biopsies show no residual tumour

Study design

A marker is placed in the centre of the tumor in all patients. After completion of NST, a total of eight 14G core biopsies are obtained at various distances form the iodine seed (4 central and 4 peripheral). Preferably, biopsies are obtained (ultra-sound guided) in the operating room while the patient is under general anaesthesia, just before surgery. Immediately hereafter, the pre-planned surgical resection of the area surrounding the marker is performed. In participating hospitals where it is not possible to obtain biopsies in the operating room due to logistic reasons, biopsies may be obtained in the outpatient clinic under ultrasound or stereotactic guidance.
Pathology results of biopsy material and surgical specimen will be compared. This allows us to establish the biopsy location and minimum number of biopsies per patient required to accurately assess pCR. Pathology results of the biopsies will be compared with data on imaging, patient and tumour characteristics. A pCR is defined as no residual tumour cells seen at microscopy.

Study burden and risks

Participation in this study will involve 8 extra biopsies. When biopsies are obtained in the operating room while the patients is already under anaesthesia, we do not expect any burden or risks. Operation time will be prolonged with approximately 20 minutes.
When the extra biopsies are obtained in the outpatient clinic, extra burden for the patient may consist of discomfort during and following the biopsy procedure. Biopsies obtained in the outpatient clinic will be obtained under local anaesthesia If possible, a pre-existing biopsy scar will be used in order

to minimize the number of biopsy scars.

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

- Age * 18 years
- Primary breast cancer, any T-stage, any N-stage
- Invasive carcinoma of the breast
- Tumour histology and receptor status established by pre-NST core biopsy
- Neoadjuvant systemic therapy (with at least 1 regime of chemotherapy)
- MRI performed prior to NST
- MRI scan after NST showed radiologic complete or partial response (0.1 * 2.0 cm contrast enhancement, *30% decrease in tumor size, according to RECIST 1.1 criteria) on MRI*
- Correct position of the marker at the center of the original tumour bed

- Written and signed informed consent;* NB: When a patient showed radiologic complete response on MRI before the last course of NST and the patient does not wish to undergo an additional MRI after NST, the patient may be included in the MICRA trial. When a patient showed partial response on MRI before the last course of NST and the patient does not wish to undergo additional MRI after NST, the patient may NOT be included in the MICRA trial.

Exclusion criteria

- Contra-indications for MR imaging
- Ductal carcinoma in situ as shown by core biopsy pre-NST
- Distant metastatic disease
- Prior radiotherapy or surgery of the ipsilateral breast

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	14-06-2016
Enrollment:	575
Type:	Actual

Ethics review

Approved WMO

Date:	05-04-2016
Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

Approved WMO Date:	25-07-2017
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	01-03-2019
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	05-04-2019
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	10-05-2019
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

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	NL56181.031.15