Tumor response assessment in breast cancer patients receiving neoadjuvant systemic therapy using optical mammography: the Softscan Study

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Primary Objective:* To investigate the value of the Softscan in the early prediction of tumor response (RECIST criteria) to neoadjuvant chemotherapy or hormonal therapy in breast cancer. Secondary Objective:* To assess the accuracy of the Softscan…

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

Summary

ID

NL-OMON36040

Source
ToetsingOnline

Brief title
The Softscan Study

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
breast cancer, mammacarcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Breast cancer, Optical imaging, Softscan, Tumor response

Outcome measures

Primary outcome

Differences in mean change of the Softscan parameters (HbO2, Hb, %water and scattering power) from the baseline to the different time intervals (1/6th, halfway, before surgery) between pathological responders and nonresponders

Secondary outcome

Difference of the change of the mean Softscan parameters in the tumor to the change in size and blood flow measured in the MRI and change in size during clinical assessment at the different time intervals.

Difference in mean tumor size (cm) measured by the Softscan compared to MRI, ultrasound and clinical assessment.

Differences between the Softscan mean parameters for the different tumor characteristics (tumor size, menopausal status, histological type, tumor differentiation grade) at baseline and prior to surgery to patient.

Study description

Background summary

Early detection of a poor response to neoadjuvant systemic treatment in breast cancer is of great importance to be able to start a beter treatment and to

reduce the time that a patient is exposed to unnecessary and potentially harmful treatment. However, the assessment of early tumor response to neoadjuvant therapy remains one of the main challenges in breast cancer. Current imaging modalities, such as MRI, are not optimal due to their sole ability to detect anatomical changes and not to detect early physiological changes. Optical imaging using near-infrared (NIR) light (700-900 nm) has recently emerged as a promising alternative technique to visualize tumor tissue and metabolic activity. Therefore, optical NIR imaging could offer the opportunity of non-invasive in vivo monitoring of the response of the primary tumor to neoadjuvant treatment.

Study objective

Primary Objective:
* To investigate the value of the Softscan in the early prediction of tumor response (RECIST criteria) to neoadjuvant chemotherapy or hormonal therapy in breast cancer.

Secondary Objective:
* To assess the accuracy of the Softscan in tumor size calculations in comparison to MRI, mammography or ultrasound at baseline.
* To assess the correlation between tumor response according to the Softscan parameters (HbO2, Hb, %water and scattering power) and MRI parameters.
* To assess the correlation between changes in the Softscan parameters and patient or tumor characteristics
* To assess new algorithms in data processing able to increase accuracy of the Softscan and enhance response prediction.

Study design

* Feasibility study to evaluate the diagnostic value of the Softscan in detection of early tumor response to neoadjuvant treatment.
* One Softscan device is installed and is operational at the LUMC
* Softscan scans will be made at baseline, at 1/6th of the treatment, halfway treatment, and before surgery. (Figure 3)
* MRI scans will be made as part of standard-of-care (LUMC guidelines: at baseline, halfway treatment and before surgery) or on request of the attending physician.
* 32 patients are required for the group to receive chemotherapy (with or without hormonal therapy) and 10 patients for the hormonal therapy alone.

Study burden and risks

This study will require patients during their period of neoadjuvant treatment for 4 visits for a scan. These scans will take about 30 - 45 minutes and are not painful to the patient.

Risks of the Softscan are limited to mild temporarely musculoskeletal pain, Additionally, there is the minimal chance of a allergic reaction of the skin to the optical medium fluids.

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

breast cancer patients to receive neoadjuvant systemic therapy

Exclusion criteria

breast implants

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-03-2011
Enrollment:	42
Type:	Actual

Medical products/devices used

Generic name:	Optical mammography;Softscan
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	19-08-2011
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL35974.058.11