Clinical evaluation of Contrast Enhanced Breast CT to improve Staging and treatment follow up in women with breast cancer

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a. Staging of women with breast cancer, particularly those with extensive carcinoma in situ (DCIS):1) The concordance of tumor extent between CEBCT and large section histopathology2) The non-inferiority of CEBCT to contrast enhanced breast MRI for...

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

Summary

ID

NL-OMON54169

Source
ToetsingOnline

Brief title
CEBCT vs MR

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
breast cancer, Mamma carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum

Source(s) of monetary or material Support: VIDI

Intervention

Keyword: breast cancer, contrast enhanced BCT, contrast enhanced MR, mamma carcinoma

Outcome measures

Primary outcome

Objective a.

The primary objective of this study is to perform a prospective clinical trial to compare the performance of CEBCT to that of the MRI for staging of women with breast cancer. The endpoint is a statistically significant difference in the accuracy of tumor size estimation with CEBCT and MRI computed from the area under the receiver operating characteristic (ROC) curve (AUC) resulting from independent interpretation of MRI images and the CEBCT images.

Objective b.

The primary objective of this study is to perform a prospective clinical trial to compare the performance of CEBCT to that of the MRI for the evaluation of residual tumor in women who have undergone primary systemic therapy. The endpoint is a statistically significant difference in the accuracy of tumor size estimation with CEBCT and MRI computed from the area under the receiver operating characteristic (ROC) curve (AUC) resulting from independent interpretation of MRI images and the CEBCT images.

Secondary outcome

As secondary objectives, we will record the frequency of contralateral cancers and their final pathological outcome, morphological and enhancement

characteristics of cancers on CEBCT complementary to existing subtyping.

Study description

Background summary

Breast CT is a novel modality that has not been largely evaluated in a clinical setting. Only recently FDA and CE marked BCT machines have been released, and the number of installed bases internationally is below 10 (although rapidly rising).
Internationally only a few studies on contrast enhanced breast CT have been performed in small numbers of patients, albeit with excellent results. Nevertheless, substantial evidence for this novel modality is still absent. In particular, the correlation of enhancement and histological grade of DCIS, correlation of CEBCT findings with histopathology, and prediction and assessment of primary systemic treatment are open fields for which more substantial evaluation is clearly needed.

Study objective

a. Staging of women with breast cancer, particularly those with extensive carcinoma in situ (DCIS):
1) The concordance of tumor extent between CEBCT and large section histopathology
2) The non-inferiority of CEBCT to contrast enhanced breast MRI for tumor staging
3) The frequency of detection of contralateral cancers with CEBCT in women with breast cancer

b. Evaluation of women treated with primary systemic therapy.
1) Is CEBCT useful for the post-systemic, pre-surgical determination of residual disease in order to minimize the extent of resection?
2) Are the morphological and enhancement characteristics of cancers on CEBCT complementary to existing subtyping for predicting response to primary systemic therapy?
3) Can CEBCT predict response to primary systemic therapy early in treatment?

Study design

All participants will undergo a bilateral CEBCT scan using a dedicated breast CT scanner (Koning, USA). This scanner creates full 3D volumes of the breast using conebeam reconstruction. The scanner is designed as an exam table, on which the patient is in prone position during image acquisition. Centrally in the table a horizontal CT gantry is positioned. A mammographic x-ray tube and

an x-ray flat panel detector are mounted on the CT gantry and circle the breast during acquisition in 10 seconds. For CEBCT two acquisitions need to be obtained (1 before and 1 after contrast), and we will perform the CEBCT of both breasts.
Prior to the examination an iv-canula will be inserted for contrast administration during the procedure. Like in (contrast enhanced) mammography the breasts are imaged one at a time. The breast to be imaged is suspended through the central table opening into the imaging space. In the clinical protocol we will first image the non-affected breast prior to contrast administration. Subsequently, the patient is repositioned and the affected breast will be imaged. Thereafter an iodinated contrast agent is administered (0.1 mmol/kg) using a power injector. Considering sufficient of time after contrast administration the affected breast will be scanned again. Finally, the non-affected breast is repositioned in the gantry, and a post-contrast acquisition of this breast is obtained as well.

Study burden and risks

CT imaging is associated with risks related to the use of radiation and contrast administration. The risks of this study are reduced as much as possible. In breast CT only the breast is exposed to radiation, sparing the rest of the chest to any significant amount of radiation. Although, these patients already get numerous mammographic views during standard clinical care. There is most probably no effect due to the level of additional radiation involved in breast CT imaging, considering the course of treatment of the study population (mastectomy or post-surgery radiation therapy).

The introduction of an imaging technology that will improve staging and treatment follow up of breast cancer detection, will have impact on survival rate and quality of life of breast cancer patients. By optimizing the image quality of this modality we will ensure that this impact on women*s healthcare is maximized. The research will not be directly beneficial to the subjects since the research breast CT results will not influence the subject*s treatment, if any.

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

- Women >18 years old
- Diagnoses of breast cancer
- Scheduled for a pre-surgery staging contrast enhanced breast MRI
- Eligible for primary systemic therapy

Exclusion criteria

- Women with suspected or confirmed pregnancy
- Women with prior breast cancer
- Women who are breastfeeding
- Women who are very frail and unable to cooperate
- Women who cannot give informed consent
- Contra indication of iodine contrast
- Contra indication for irradiation (i.e. genetic mutation that predispose to breast cancer)
- Male subjects

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):	18-04-2023
Enrollment:	413
Type:	Actual

Medical products/devices used

Generic name:	Computed Tomography (CT)
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	05-04-2022
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	26-01-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	14-09-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL75855.091.21