# Clinical evaluation of Contrast Enhanced Breast CT in women recalled from screening due to calcifications

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Sensitivity of CEBCT for DCIS when focal enhancement around calcifications is deemed positive, and no enhancement is regarded as a negative test outcome.

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

## Summary

### ID

NL-OMON56633

**Source**
ToetsingOnline

**Brief title**
CEBCT-Calcs

### Condition

- Breast neoplasms malignant and unspecified (incl nipple)

**Synonym**
breast cancer, Mamma calcifications

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Radboud Universitair Medisch Centrum
**Source(s) of monetary or material Support:** VIDI

## Intervention

**Keyword:** Breast cancer, Calcifications, Contrast enhanced BCT, Mamma carcinoma

## Outcome measures

### Primary outcome

The primary endpoint of this study is the prevention of unnecessary biopsies and the non-invasive distinction between low grade (indolent) ductal carcinoma in situ (DCIS), and higher grade (potentially lethal) disease. In particular, prevention of the unnecessary biopsies will be a justified alternative solution, depending on the sensitivity of CEBCT for DCIS when focal enhancement around calcifications is deemed positive and no enhancement is regarded as a negative test outcome. In order to propose such a follow-up process instead of the stereotactic biopsy, reliable and high-performance metrics are needed.

### Secondary outcome

1. the frequency of enhancement on CEBCT near calcifications with a benign origin

In order to calculate the frequency rate of enhanced areas on CEBCT near calcifications, the gold standard of histopathological verification is needed to identify their benign origin.

2. the association between enhancement patterns and histological grade of the disease

Since the amount of enhancement is related to the aggressiveness of DCIS, we infer that signal intensities in CEBCT will also reflect biological

aggressiveness.

# Study description

### Background summary

Breast Computed Tomography (BCT) is a new three-dimensional (3D) imaging technology that has yet to be thoroughly tested in a clinical environment. BCT machines were only recently FDA and CE approved, and the number of installed devices worldwide is around ten (although rapidly rising). Only a few studies using contrast enhanced breast CT have been conducted in small groups of patients internationally, albeit with promising outcomes. Despite this, there is no considerable clinical evidence for the principal role of BCT in various indications (screening, diagnosis, prognosis). Specifically, the work-up of patients recalled from screening due to calcifications and their relevant association with aggressive (higher grade) DCIS are still open issues that need to be solved, to improve primary prevention.

### Study objective

Sensitivity of CEBCT for DCIS when focal enhancement around calcifications is deemed positive, and no enhancement is regarded as a negative test outcome.

### Study design

Observational multicenter cohort study.
All recruited patients recalled from screening (mammography) follow the diagnostic work up undergoing a Digital Breast Tomosynthesis (DBT) examination. On top of that a bilateral CEBCT scan using a dedicated breast CT scanner (Koning, USA) is integrated in the breast imaging part of the study. The standard clinical practice of stereotactic biopsy follows, in which the histopathological analysis stages malignant lesions with respect to their aggressiveness.

### Study burden and risks

The main risks associated to performing CEBCT examinations are related to the use of ionizing radiation and that of contrast agent administration. The risks of this study are reduced as much as possible. Although the additional radiation to which the woman is exposed during CEBCT (one pre- and one post-contrast acquisitions are needed) amounts to double that of diagnostic mammography, the associated risk is considered to be relatively low when compared to the benefits that it can bring.1-3 During breast CT examinations only the breast is exposed to ionizing radiation, sparing the rest of the chest

to any significant amount of ionizing radiation.
Additionally, by performing CEBCT the diagnostic yield of biopsies (i.e., the percentage of biopsies that show cancer), which is currently of only ~20%,4 will be increased. This will be achieved since calcified lesions that enhance at CEBCT, which are more often associated to DCIS5,6, will be biopsied, while those that do not enhance, normally representing benign microcalcifications, will not be biopsied. Moreover, avoiding biopsy has positive effects on women, who are spared from the stress related to both the invasive procedure and the anxiety of the results of the biopsy.
Finally, the risks related to contraindications or potential adverse reactions for iodine-based contrast agents (allergies, nephropathy) need to be assessed prior to the CEBCT imaging examination for each single patient (see appendix A (Radboudumc specific) and appendix B (NKI specific)).

The introduction of an imaging technology such as CEBCT will allow for improvement of the standard current clinical workup of recalled microcalcifications, which translates into prevention of invasive breast cancer. 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 care pathway. However, results of this research study may impact the potential clinical examinations of thousands of women annually. In particular, for women recalled for calcifications at screening mammography it will reduce the overdiagnosis and the number of painful biopsies of relatively harmless abnormalities.

## Contacts

**Public**
Radboud Universitair Medisch Centrum

Geert Grooteplein 10
Nijmegen 6500HB
NL
**Scientific**
Radboud Universitair Medisch Centrum

Geert Grooteplein 10
Nijmegen 6500HB
NL

# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

## Inclusion criteria

- Women 50 to 75 years old
- Recalled from screening due to calcifications
- Planned to go for stereotactic biopsy

## Exclusion criteria

- Women with prior breast cancer
- Women who are very frail and unable to cooperate
- Women who cannot give informed consent
- Contraindication of iodine contrast (i.e., contrast allergy, renal function impairment (GFR >=60 mL/min/1.73m2))
- Contraindication for irradiation (i.e., genetic mutation that predispose to breast cancer)
- Male subjects

# Study design

## Design

**Study type:** Observational invasive

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

### Recruitment

NL

| | |
|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 01-05-2023 |
| Enrollment: | 539 |
| Type: | Anticipated |

### Medical products/devices used

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

## Ethics review

Approved WMO

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| Date: | 12-03-2024 |
| Application type: | First submission |
| 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 | NL82330.091.22 |