# Dual-layer spectral computerized tomography for breast cancer detection in women with dense breasts: a single centre, feasibility study.

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The main objective of this project is to demonstrate the feasibility of DLSCT to detect breast cancer in women with dense breasts.

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

## Summary

### ID

NL-OMON50792

**Source**
ToetsingOnline

**Brief title**
The DECREAS study.

### Condition

- Breast neoplasms malignant and unspecified (incl nipple)
- Breast disorders

**Synonym**
Mammary cancer

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Rijnstate Ziekenhuis

**Source(s) of monetary or material Support:** Eigen geld (andere studies).

## Intervention

**Keyword:** Breast Density, Breast Neoplasms, Computer-Assisted, Radiographic Image Interpretation

## Outcome measures

### Primary outcome

To determine the feasibility of DLSCT to detect breast cancer in women with dense breasts and histopathologically locoregional advanced primary breast cancer.

### Secondary outcome

1. To determine iodine enhancement (HU) and iodine content (mg/mL) values of tumor, normal breast tissue and pectoralis muscle in reconstructed virtual monochromatic images obtained at 40, 60, 80 and 100 keV and iodine maps

2. To correlate tumor conspicuity and BI-RADS score with the following features: size of tumor, type of tumor, MRI and PET-CT images, histologic gradation of tumor and immunohistochemical staining results

# Study description

### Background summary

Breast cancer is one the most commonly diagnosed cancers among women with an incidence rate of 89.7 per 100.000 women in Western Europe. The decline in the mortality rate of the last few decades is mainly contributable to the great developments both at the diagnostic and therapeutic field. However, breast cancer still is responsible for more than 500.000 deaths annually and therefore it remains the leading cause of cancer-related mortality worldwide. Mammographic dense breast tissue is recognized as a major independent absolute risk factor for the development of breast cancer, which is present in about 50% of women over the age of 40 years. Breast cancer can be easily missed at the

routinely screening mammography due to the masking effect of dense breast tissue in these patients. Therefore, supplemental screening with other modalities, for example digital breast tomosynthesis (DBT), ultrasound, magnetic resonance imaging (MRI) and cone-beam breast computed tomography (CBBCT) has been recommended. Unfortunately, none of these modalities have proven to be superior. The last few years dual-layer spectral computerized tomography (DLSCT) systems have emerged to be a hot topic. This is mainly due to lower radiation exposure and contrast agent usage. Moreover, material decomposition images and iodine quantification analysis can be derived. Thereby, DLSCT could be a promising screening tool which eliminates the challenges accompanied with screening women at high-risk for breast cancer due to dense breast tissue.

### Study objective

The main objective of this project is to demonstrate the feasibility of DLSCT to detect breast cancer in women with dense breasts.

### Study design

This is a prospective, single centre, case series with 14 patients who will undergo a DLSCT scan.

### Study burden and risks

Participants will be asked to undergo a contrast enhanced DLSCT scan. Since the DLSCT scan will be performed immediately after the regular performed PET-CT scan, there will be no need for an additional visit to the hospital. In addition, the same intravenous access will be used for the administration of 18F-FDG and the contrast agent to minimize participant burden.
Participation in this study is associated with two potential risks. First, the administration of contrast agents can lead to adverse reactions. The majority are self-limited and predominantly involve dermatologic manifestations. Besides, our team of physicians are trained to treat potential life-threatening reactions as efficiently as possible according to local guidelines.
The second risk is related to the radiation exposure. The effective dose of each DLSCT scan will be about 2 mSv. This is classified as low risk (category IIb) which is justified because the research is directly aimed to prevent or cure disease (ICRP publication 62).

## 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

1. Females aged 18 years and over
2. Diagnosis of histopathologically proven locoregional advanced primary breast cancer:
- A. Tumors > 5 cm (= T3) or
- B. Tumors with invasion of the skin or chest wall (= T4) or
- C. Any tumor with >= 4 axillary lymph nodes or ipsilateral internal mammary, infraclavicular or supraclavicular nodal involvement (= N2-3)
3. Heterogeneously or extremely dense breasts on full-field digital mammograms: category C or D according to the ACR BI-RADS lexicon

## Exclusion criteria

1. History of allergic reactions to iodinated contrast agents
2. Pregnancy or breast feeding
3. Treatment of thyroid disease with radioactive iodine
4. Use of metformin
5. Creatinine clearance < 45 ml/min

6. Chronic or acutely worsening renal disease

# Study design

## Design

**Study type:** Observational invasive

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

## Recruitment

NL

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|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 15-02-2023 |
| Enrollment: | 14 |
| Type: | Actual |

# Ethics review

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| Approved WMO Date: | 05-08-2021 |
| Application type: | First submission |
| Review commission: | CMO regio Arnhem-Nijmegen (Nijmegen) |
| Approved WMO Date: | 20-09-2024 |
| 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 | NL76792.091.21 |