

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

Published: 05-08-2021

Last updated: 28-09-2024

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

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 ^{18}F -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

Public

Rijnstate Ziekenhuis

Wagnerlaan 55
Arnhem 6815 AD
NL
Scientific
Rijnstate Ziekenhuis

Wagnerlaan 55
Arnhem 6815 AD
NL

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

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Recruiting

Start date (anticipated): 15-02-2023

Enrollment: 14

Type: Actual

Ethics review

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