Dedicated Breast CT for Diagnosis of Breast Cancer.

Published: 20-01-2016
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We propose to perform a prospective trial to compare the accuracy of breast CT to the current standard imaging technologies for diagnosis of breast cancer in patients with a suspicious lesion identified during breast cancer screening.

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

Summary

ID

NL-OMON52995

Source
ToetsingOnline

Brief title
Breast CT.

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: National Cancer Institute;United States of America

Intervention

Keyword: Breast cancer, Computed Tomography

Outcome measures

Primary outcome

Difference in ROC area under the curve of breast CT vs. standard work-up for

diagnosis of breast cancer.

Secondary outcome

Sub-analysis for difference in ROC area under the curve of breast CT vs.

standard work-up for diagnosis of breast cancer divided by type of lesion.

Study description

Background summary

Of the many novel imaging technologies being developed for breast cancer imaging, dedicated breast computed tomography (BCT) is one of very few that results in a true tomographic image of the breast with high contrast resolution and does not require the injection of a contrast agent or radiopharmaceutical. This makes it ideal for use as the frontline imaging technology for working up suspicious lesions detected during breast cancer screening or during clinical breast examination.

Study objective

We propose to perform a prospective trial to compare the accuracy of breast CT to the current standard imaging technologies for diagnosis of breast cancer in patients with a suspicious lesion identified during breast cancer screening.

Study design

Prospective single arm study with all participants undergoing standard of care plus breast CT. Observer study will retrospectively evaluate breast CT and standard images and recommendations for biopsy/no biopsy compared to final clinical outcome.

Study burden and risks

In addition to the imaging performed as the standard of care, participants will be imaged with the breast CT system. Imaging involves 5 minutes for positioning and 10 seconds for the actual image acquisition. The rest of the time burden involves providing the subjects with the information on the study, answering their questions, and obtaining informed consent. The risk associated with the radiation involved is similar to that of the standard diagnostic work-up, since the level of radiation dose is similar. There is no direct benefit to the participants, but the benefit to the society involves the investigation of a new imaging technology to improve the diagnosis of breast cancer after screening.

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 age 35 or older
- Women scheduled to undergo a diagnostic work-up following an abnormal screening mammogram (BI-RADS 0) with the suspicious finding NOT located in the axillary tail of the breast.
- Women who underwent diagnostic work-up following an abnormal screening mammogram and were assigned a BI-RADS 4 or 5 due to soft tissue lesions, or due to microcalcifications with the suspicious finding NOT located in the axillary tail of the breast.

Exclusion criteria

- Women who do not meet the inclusion criteria
- Women with suspected or confirmed pregnancy
- Women who have had bilateral mastectomy
- Women whose suspicious lesion is located in the axillary tail
- Women with prior breast cancer or breast biopsy in the recalled breast in the last 12 months
- Women with palpable lesions
- Women who are breastfeeding
- Women who are very frail and unable to cooperate
- Women who cannot give informed consent
- Male subjects

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-10-2016

Enrollment:	340
Type:	Actual

Medical products/devices used

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

Ethics review

Approved WMO Date:	20-01-2016
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	05-10-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	14-11-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	17-09-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	18-11-2020
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	10-05-2022
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	NL55378.091.15

Study results

Date completed: 09-01-2024

Actual enrolment: 210

Summary results
Trial ended prematurely