Diagnostic value of three-dimensional ultrasound in breast cancer screening participants referred with a BI-RADS 0 test result: a comparison of imaging strategies

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To investigate the diagnostic value of 3DUS as a standalone imaging modality as well as in combination with conventional imaging modalities to diagnose breast cancer in Dutch breast cancer screening participants with a BI-RADS 0 mammography result.

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-OMON47752

Source
ToetsingOnline

Brief title
Diagnostic value of three-dimensional breast ultrasound

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
breast cancer, breast neoplasm

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: General Electric Company,General Electric Healthcare

Intervention

Keyword: Breast Cancer, Breast Neoplasms, Breast Ultrasonography, Three-dimensional Ultrasound

Outcome measures

Primary outcome

The primary outcome is the accuracy of different imaging strategies in diagnosing breast cancer, expressed as the area under the receiver operating characteristic (ROC) curve. Pathology or the results of all imaging modalities are used as the reference standard. All study participants will be followed up to the next scheduled screening round approximately 2 years later to determine if any breast cancer was missed. The imaging modalities under study, supplemental to the full-field digital screening mammography, are 3DUS, digital breast tomosynthesis (DBT) and handheld ultrasound (HHUS).

Secondary outcome

The diagnostic accuracy of the different imaging strategies among subgroups of patients based on mammographic density and age.

The biopsy referral rate for the different imaging strategies under study.

The interobserver reliability for 3DUS.

Study description

Background summary

Population-based mammography screening has proven successful in decreasing breast cancer mortality due to breast cancer detection and treatment at an early stage. However, one of the main disadvantages of screening is a false-positive test result, leading to a costly diagnostic work-up of a non-malignant lesion, adverse psychological consequences and pressure on health care facilities, especially when an additional biopsy is necessary. In 2014 17,7 per 1000 women screened received a false positive result, in almost one third of these women (32.2%) invasive assessment was necessary. The highest percentage of non-malignant biopsies has been observed among the participants referred with a BI-RADS 0 result, the latter group representing 60% of all referrals. Therefore, the need for improvement of the supplemental imaging strategy, leading to the smallest number of biopsy referrals without missing any cancers, is most urgent among screening participants with a BI-RADS 0 test result.
Three-dimensional ultrasound (3DUS), a new imaging technique that enables the acquisition of volumetric images of the whole breast, is likely to play a major role in this improvement. Several studies have been performed on the diagnostic accuracy of 3DUS, showing promising results. However, the lesion detection, reliability and interobserver variability needs to be confirmed before this technique is implemented in the imaging strategy for BI-RADS 0 referrals. Therefore, the proposed study aims to investigate the diagnostic value of 3DUS in Dutch screening participants referred with a BI-RADS 0 mammography result.

Study objective

To investigate the diagnostic value of 3DUS as a standalone imaging modality as well as in combination with conventional imaging modalities to diagnose breast cancer in Dutch breast cancer screening participants with a BI-RADS 0 mammography result.

Study design

Multicenter diagnostic study.

Study burden and risks

Participation in this study will mean that a patient undergoes a bilateral 3DUS in addition to conventional imaging. The procedure is associated with minimal burden; some patients might experience discomfort to mild pain during the acquisition due to mild breast compression. Furthermore, 3DUS will take 15-20 minutes of time investment per patient. Participating patients might benefit from the extra 3DUS as we hypothesize that the addition of the 3DUS to conventional imaging will provide the highest diagnostic accuracy.

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

Participants of Dutch breast cancer screening with a BI-RADS 0 mammography result, who are referred to one of the participating hospitals for further diagnostic work-up.

Exclusion criteria

Inability to understand study information

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):	05-04-2018
Enrollment:	600
Type:	Actual

Ethics review

Approved WMO Date:	07-11-2017
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	12-09-2018
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 29659
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL61243.041.17
OMON	NL-OMON29659