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

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON29659

Source
Nationaal Trial Register

Brief title
TURB0

Health condition

Breast Neoplasms
Breast Cancer
Breast Ultrasonography
Three-dimensional Ultrasound
Borstkanker
Mammacarcinoom
Echografie Mammae
Driedimensionale Echografie

Sponsors and support

Primary sponsor: University Medical Center Utrecht
Source(s) of monetary or material Support: General Electric Healthcare

Intervention

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 and handheld ultrasound.

Secondary outcome

Secondary outcomes include the diagnostic accuracy of the different imaging studies for subgroups of patients based on age and mammographic density. Furthermore, the biopsy referral rate for the different imaging strategies and the interobserver reliability for 3DUS will be determined.

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 multicenter diagnostic study aims 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. The primary outcome is the accuracy of different imaging strategies in diagnosing breast cancer, expressed as the area under the receiver operating characteristic curve. Pathology or the results of all imaging modalities are used as the reference standard. Follow up imaging of all study participants up to 2 years after inclusion will be checked for any breast cancer cases that were missed. The imaging modalities under study, supplemental to the full-field digital screening mammography, are 3DUS, digital breast tomosynthesis and handheld ultrasound.

Study objective

Addition of threedimensional breast ultrasound to the conventional diagnostic workup improves diagnostic accuracy in women referred from breast cancer screening with a BI-RADS 0 test result.

Study design

All imaging is performed when the patient visits the hospital after referral from breast cancer screening with a BI-RADS 0 test result. Patients are followed up to the next scheduled screening round (approximately 2 years later) to determine if any breast cancer was missed.

Intervention

Addition of a bilateral threedimensional breast ultrasound to the conventional diagnostic workup of breast cancer screening participants referred with a BI-RADS 0 test result.

Contacts

Public
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Eligibility criteria

Inclusion criteria

- Dutch breast cancer screening participants aged 50-75 years

- BI-RADS 0 screening mammography result

- Referred to one of the participating hospitals for diagnostic work-up

Exclusion criteria

- Subject is unable to understand, read and sign the study specific informed consent after the nature of the study has been fully explained to her.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	27-03-2018
Enrollment:	600
Type:	Anticipated

Ethics review

Positive opinion
Date: 27-03-2018
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 47752
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7007
NTR-old	NTR7197
CCMO	NL61243.041.17
OMON	NL-OMON47752

Study results