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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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.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON29659

Bron
Nationaal Trial Register

Verkorte titel
TURB0

Aandoening

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

Ondersteuning

Primaire sponsor: University Medical Center Utrecht
Overige ondersteuning: General Electric Healthcare

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

B.M. Dekker, den
Utrecht
The Netherlands

Wetenschappelijk

B.M. Dekker, den
Utrecht
The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	27-03-2018
Aantal proefpersonen:	600
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	27-03-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 47752
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten