Evaluation of Virtual Touch Tissue Imaging Quantification (VTIQ - 2D-SWE) in the Assessment of BI-RADS® 3 and 4 lesions: Can patient selection for biopsy be improved? - A confirmatory Multi-Center-Study

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The main objective of this study is to improve the power of breast ultrasound examinations by evaluating tissue alterations by means of Elastography. Recent studies have shown that there is a correlation between stiffness and malignancy of tissue....

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-OMON43355

Source
ToetsingOnline

Brief title
VTIQ

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
breast lesion, breast tumor

Research involving

Human

Sponsors and support

Primary sponsor: Jeroen Bosch Ziekenhuis
Source(s) of monetary or material Support: Siemens

Intervention

Keyword: benign, elastography, malignant, Virtual Touch IQ

Outcome measures

Primary outcome

1) To assess whether ultrasonically visualized breast lesions, categorized as BI-RADS® 4a, with a VTIQ-measured shear velocity value of smaller than or equal to 3.5 m/s (37 kPa), show a lower malignancy rate than BI-RADS® 4a with a VTIQ-measured shear velocity value of larger than 3.5 m/s (37 kPa).

2) To assess whether the malignancy rate of ultrasonically visualized breast lesions categorized as BI-RADS® 4a with a VTIQ-measured shear velocity value of smaller than or equal to 3.5 m/s (37 kPa) is below 2%.

3) To assess whether the malignancy rate of ultrasonically visualized breast lesions categorized as BI-RADS® 3 with a VTIQ-measured shear velocity value of smaller than or equal to 3.5 m/s (37 kPa) is below 2%.

Secondary outcome

1) To assess whether ultrasonically visualized breast lesions, categorized as BI-RADS® 3 with a VTIQ-measured shear velocity value of smaller than or equal to 3.5 m/s (37 kPa), show a lower malignancy rate than BI-RADS® 3 with a

VTIQ-measured shear velocity value of larger than 3.5 m/s (37 kPa).

2) To assess whether ultrasonically visualized breast lesions, categorized as BI-RADS® 4b with a VTIQ-measured shear velocity value of smaller than or equal to 3.5 m/s (37 kPa), show a lower malignancy rate than BI-RADS® 4b with a VTIQ-measured shear velocity value of larger than 3.5 m/s (37 kPa).

3) To assess whether ultrasonically visualized breast lesions, categorized as BI-RADS® 4c with a VTIQ-measured shear velocity value of smaller than or equal to 3.5 m/s (37 kPa), show a lower malignancy rate than BI-RADS® 4c with a VTIQ-measured shear velocity value of larger than 3.5 m/s (37 kPa).

4) To assess whether the probabilities for malignancies predicted with ultrasonically visualized breast lesions categorized according to BI-RADS® differ from the probabilities for malignancies predicted with ultrasonically visualized breast lesions categorized with the help of VTIQ only or by a combination of BI-RADS® and VTIQ measurements.

5) To assess whether for women with ultrasonically visualized breast lesions categorized as BI-RADS® 3, 4a, 4b or 4c, respectively, the subgroup of women with a strain ratio smaller than or equal to 1 shows a lower malignancy rate than the subgroup of women with a strain ratio larger than 1.

6) To assess the VTIQ intra-rater reliability for the original continuous scale and the dichotomized values.

7) To assess, in a subgroup with valid VTIQ results, the reproducibility of VTIQ shear velocity measurements made on the same lesion in different examinations performed on the same day by different operators. To assess the VTIQ inter-rater reliability for the original continuous scale and the dichotomized values.

8) To assess predictive factors of the continuous VTIQ-value. The following factors will be examined:

Subject-related factors:

- Skin-breast lesion surface depth (cm)
- Quality factor (color coded scale) within the lesion
- Breast density/ tissue composition (homogeneous background texture fat, homogeneous background texture fibroglandular, heterogeneous background texture)
- Lesion size in B mode (cm)
- Normal fatty tissue shear wave velocity (Ratio between measurement in the fatty tissue and in the lesion)
- Pathology and Immunhistology

9) To assess the inter-rater reliability of BI-RADS® Assessment.

Local (BI-RADS® given at each site) and central expert BI-RADS® assessment will

be compared (BI-RADS® assessment and assessment of the variables leading to the BI-RADS® value separately). In addition, the BI-RADS® assessments will be compared with the histological results.

10) To examine whether the cut-off value might be increased to further reduce the number of unnecessary benign biopsies.

Study description

Background summary

In this study, only BI-RADS® categories 3 to 4c are considered.
Based on the likelihood of malignancy of up to 2% the recommendation for BI-RADS® 3 is an ultrasound follow-up in 6, 12 and 24 months, while BI-RADS® 4a and higher should be biopsied. This results in missing up to 2% of malignancies in the first place. Some of them will be detected in the follow-up examinations.
By scanning lesions with Shear Wave Elastography the stiffness of the lesion can be measured. Few studies have evaluated Virtual Touch Tissue Imaging Quantification (VTIQ) as a new Shear Wave Elastography method in breast tissue, suggesting cut-off values for the differentiation of benign and malignant lesions, showing a high reliability and reproducibility and assessing the amount of precompression needed for optimal scanning [2-8]. The most recent ACR BI-RADS® version of 2013 includes recommendations for ultrasound elastography for the first time [1].
This multi-center confirmatory study aims to improve the assessment of BI-RADS® 3 and 4a lesions by down- or upgrading lesions based on VTIQ [5, 9]. Secondly, this study aims to evaluate whether the assessment of BI-RADS® 4b and 4c cases can be improved.
All study participants will receive VTIQ in addition to standard ultrasound.
The standard BI-RADS® Ultrasound (US) category (BI-RADS® 3-4c) and VTIQ values will be correlated with the histological result.
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Study objective

The main objective of this study is to improve the power of breast ultrasound examinations by evaluating tissue alterations by means of Elastography. Recent studies have shown that there is a correlation between stiffness and malignancy of tissue. To reassess these first results and verify them by evaluating a

larger number of examinations (1000 cases) is the goal of this study. If this technique succeeds in differentiating benign from malignant tissue, less biopsies would be required in the future.

Study design

Prospective multicenter cohort study

Study burden and risks

There are no risks involved. The examination will take about 10 minutes

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

Female
Age >=18 years
Patients with a lesion >= 0.5 cm, initially scored BI-RADS® 3, 4a, 4b or 4c in B-mode ultrasound
Signed informed consent of study participation

Exclusion criteria

Pregnant or lactating women
Women with breast implants on the same side as the lesion
Women that underwent local radiation or chemotherapy within the last 12 months
Women with history of breast cancer or breast surgery in the same quadrant
Lesions in or close to scar tissue (< 1cm)
Skin lesions or lesions that have been biopsied previously
Lesion larger than 4 cm
No lesion should be included when more than 50% of the lesion is further down than 4 cm beneath the skin level

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):	20-09-2017
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	05-09-2016
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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	NL56972.028.16