Comparison of ABVS and HHUS for detection and characterization of breast lesions

Published: 09-01-2014
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1. To evaluate wether ABVS could replace HHUS in women

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-OMON38545

Source
ToetsingOnline

Brief title
Comparison of ABVS and HHUS in breast lesions

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
breast lesion

Research involving
Human

Sponsors and support

Primary sponsor: Onze Lieve Vrouwe Gasthuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: breast, cancer, ultrasound

Outcome measures

Primary outcome

1.A The number of solid lesions detected with ABVS compared to the number of solid lesions detected with HHUS in women < 30 year.

2.B Sensitivy, specificity, PPV, NPV, accuracy and diagnostic yield of ABVS and HHUS in patients with high suspicion of breast cancer.

3.C Number of additional detected lesions on ABVS and MRI in patients with a known breast cancer

Secondary outcome

1.A Consequences for patients in terms of extra biopsies and eventually follow-up studies due to ABVS

2.B Agreement in lesion characterization for ABVS and HHUS for specific features; orientation, echogenicity, margins, acoustic shadow and size.

3.C Comparison of malignancy features of MRI (enhancement, echogenicity, borderlines, size) versus ABVS

Study description

Background summary

Breast cancer is the most common malignancy in Dutch women with a life prevalence of 10%. A nation wide screeningsprogram *Bevolkins Onderzoek naar Borstkanker* (in short BOB) is designed to screen in early phase to detect breast cancer. Next to this program, breast cancer may be detected by the finding of a palbaple breast mass. A palpable breast mass in women older than 30 years requires mammography (XMG) and ultrasound (Hand Held Ultra Sound or

HHUS). In women younger than 30 years the first diagnostic step is ultrasound imaging. The reason therefore is that mammograms are summation images and younger women have relatively dense breast tissue, which hampers proper interpretation of the mammography. This makes ultrasound the first diagnostic tool in patients <30 years. Thus, ultrasound plays an important role in the diagnostic imaging of breast masses.

Next to this ultrasonography is also of major importance when an abnormality is found on mammography in older women. When a mammographic abnormality is detected, it can be difficult to precisely define and characterize, and at this time ultrasound is used to assess the nature of a lesion, extent of disease and it can indentify additional invasive lesions. The next advantage of ultrasound is that it can easily be used as guidance for punctions and biopsies to acquire histology of a lesion. The disadvantage of HHUS is that quality of imaging is highly operator dependent and thus moderate reproducible and reliable.

Recently a new technique has been introduced, semi-automated 3-dimensional utrasonography also called Automated Breast Volume Scan (ABVS). Using this technique the physician assistant will set up the 3D ultrasound and automated images of the whole breast are acquired, thus resulting in a standardized image data set. This makes the technique operator independent and facilitates image analysis. Previous studies are promising but small and have shown that more relevant lesions may be detected with improved reproducibility to HHUS, however significant conclusions could thusfare not be drawn.

Study objective

1. To evaluate wether ABVS could replace HHUS in women <30 year with focal breast signs
2. To evaluate the performance of ABVS in comparison to HHUS in patients with high suspicion of breast cancer
3. To start a pilot study to compare ABVS with breast MRI in patients with known breast cancer

Study design

Prospective diagnostic monocenter study.
For the 3 objectives we discriminate 3 cohorts.

A. Women < 30 year with a palpable mass. Women < 30 years who have a palbable mass, have a low chance of having a malignancy. The general practicioner will refer these women to the radiologist for ultrasound examination. The most common causes of a palpable breast mass in these young patients are cystic lesions, solid lesions and dense glandular tissue. When a solid lesion is detected, a choice can be made between expectative policy with 6 months follow-up or immediate biopsy. In other cases, no further follow-up is

required. HHUS will be performed by one of the staff radiologists or resident under supervision of a staff member, such as is common in daily practice. We strive to perform ABVS immediatly after the HHUS, but certainly within 5 days.

B. Women with a high suspicion of breast cancer. These women may have a palpable breast mass or an abnormality was found during screening and are usually older than 30 year. In these patients first a standard XMG is done. However, by XMG only, it can be difficult to determine the nature of a detected abnormality. XMG cannot certainly discriminate between a cystic or solid nature of lesion, and also the exact extent and borderlines may be difficult to define. Therefore ultrasound is indicated. According to the guidelines all patients with high risk lesions require pathology-analysis by means of histologic biopsy. Most of these biopsies are ultrasound guided. The patients will first be send to the mammacare department for clinical examination followed by XMG and HHUS imaging. ABVS will be performed after this conventional imaging is performed, but always within 5 days.

C. Women with proven malignancy who require breast MRI. These patients have already had biopsy, but pathology, clinical presentation and imaging are incorcordant or have a suspected multifocal tumor. MRI is planned before the proper treatment can be defined and ABVS will be performed after or before MRI, but always within 5 days.

In all cohorts, images will be independently analysed by one the four dedicated breast radiologists. Reporting will be perfomed according to the BIRADS classification system, inlcuding number, characterization, classification and location.

Study burden and risks

Both the presence of a palpable breast lesions of unknown origin as well as a known breast tumour, carry severe distress and anxiety for most women. Next to that patients are very worried about the required additional imaging studies and possible biopsy. Ultrasound gives no radiation harm and has no other known side effects. Although this study implies some extra time for the patient, the women are ensured that both breasts are fully examined. If no lesion is found this could be very satisfying and reassuring. On the other hand, if extra lesions are found, immediate action will be undertaken to analyse this and make a final decision. Finally this may results in improved diagnostics and thus better treatment. If this is true, in future ABVS could be used to replace HHUS and provide a better standard imaging technique.

Contacts

Public
Onze Lieve Vrouwe Gasthuis

Oosterpark 9
Amsterdam 1090HM
NL
Scientific
Onze Lieve Vrouwe Gasthuis

Oosterpark 9
Amsterdam 1090HM
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Young women with focal breast signs
Women with a high suspicion of breast cancer

Exclusion criteria

Physically handicapped
Post mastectomy

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):	01-10-2012
Enrollment:	750
Type:	Actual

Medical products/devices used

Generic name:	Automated Breast Volume Scanner
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	09-01-2014
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL46703.100.13