Feasibility of Using 3D Ultrasound in Breast Cancer Screening of Women with High Risk.

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The main objective of this study is to determine the performance of whole breast scanning with ultrasound (WBUS), combined with MRI, in a yearly breast cancer screening program for high-risk women, compared to the current practice of the combination...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Breast neoplasms malignant and unspecified (incl nipple)
Study type	Observational non invasive

Summary

ID

NL-OMON31668

Source
ToetsingOnline

Brief title
3D Ultrasound in Breast Cancer Screening.

Condition

- Breast neoplasms malignant and unspecified (incl nipple)
- Breast disorders

Synonym
Breast carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Breast Carcinoma, Carriers, Screening, Ultrasound

Outcome measures

Primary outcome

Main study parameter is the difference in detection performance between WBUS

and mammography.

Detection performance is measured by detection rate, specificity, and area

under the ROC based on BIRADS scores.

Secondary outcome

Patient compliance.

Study description

Background summary

Handheld ultrasound plays an important role in the diagnosis of breast cancer but is currently not used in screening, because scanning of the breast with the available transducers is generally considered to be too time-consuming and too limited by its viewing angles for whole breast evaluation.
Recently a new device became available that allows automated whole breast scanning (3D Whole Breast Ultrasound [SomoVuTM]). With this technology ultrasound may be transformed into an important modality for breast cancer screening.
In particular in younger women with BRCA 1/2 mutation and dense breasts it may outperform x-ray mammography, with the advantage of avoiding the use of radiation. This is of great importance, as BRCA 1/2 carriers are more susceptible to radiation induced breast carcinoma than non-carrier women.
Regular surveillance in women with high genetic or familial risk of breast cancer is currently carried out in a protocol including MRI and mammography (yearly) , and with clinical examination (every 6 months).

Study objective

The main objective of this study is to determine the performance of whole breast scanning with ultrasound (WBUS), combined with MRI, in a yearly breast

cancer screening program for high-risk women, compared to the current practice of the combination of mammography and MRI.
Secondly, to assess the potential of WBUS in detecting -interval- tumors in the 6 month interval now present in the current screening program.
Further objectives are the development of guidelines to optimise image acquisition and interpretation.

Study design

A prospective design will be used to investigate the detection accuracy of WBUS in an ongoing yearly breast cancer screening program for high risk women utilizing mammography and MRI.
A WBUS exam will be carried out every 6 months during a study period of two years. Sensitivity and specificity will be compared to that of annual MRI and mammography exams.

Study burden and risks

Use of ultrasound in breast imaging is not associated with any known hazards.
The extra burden for the participants will be kept to a minimum by scheduling the exams at the time they visit the clinic for their regular screening exams (every 6 months).
The exam itself is not discomforting and takes approximately 15 minutes.

The greatest benefit of the exam is expected at the visits where only physical examination is currently conducted.
The current data suggest that the progression rate of breast neoplasia is accelerated in women who carry BRCA1/2 deleterious mutations compared with other patients who have breast carcinoma with or without a family history. This increased progression rate should be taken into account when considering the surveillance of asymptomatic women and a 6 months advancement in cancer detection is therefore important [46, 47].
With WBUS cancers may be detected that would otherwise remain undetected until the next screening exam utilizing MRI and mammography.

A negative side effect is an expected increase of needle biopsies.

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

Women who are carriers of the BRCA-1 or BRCA-2 gene.

Exclusion criteria

Bilateral breastamputation

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	07-10-2010
Enrollment:	300
Type:	Actual

Ethics review

Approved WMO

Date:	26-11-2009
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL18320.091.08