Clinical pilot study of 3D-cup ultrasound of the breast

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a) to analyze and optimize the image quality of this prototype 3D-scanner. b) to assess the potential of the 3D-scanner to detect lesions (benign and malignant) in the breast and c) to assess the potential to determine the localization of lesions in...

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

Summary

ID

NL-OMON31253

Source
ToetsingOnline

Brief title
3D-cup breast ultrasound

Condition

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

Synonym
breast lesions

Research involving
Human

Sponsors and support

Primary sponsor: Philips Research
Source(s) of monetary or material Support: Philips Research

Intervention

Keyword: 3D, automated, breast, ultrasound

Outcome measures

Primary outcome

optimal transducer geometry and system-set up of Cupidus 3D ultrasound

comparison between 2D and 3D US for visualization of lesions and strucures in

the breast

Secondary outcome

number and nature of artifacts in 3D images

Study description

Background summary

X-ray mammography is of limited use in screening for breast cancer in young women (with often dense breasts). Mammography is often painful due to compression of the breasts and it makes use of radiation. There is therefore a need for a noninvasive, harmless method for screening for breast cancer in young women at risk for developing breast cancer. Thus far the role of ultrasound (US) in screening is disputable since with conventional 2D US it is difficult to convincingly image the entire breast. The proposed automated 3D method will make breast US largely investigator-independent and probably more reproducible.

Study objective

a) to analyze and optimize the image quality of this prototype 3D-scanner.
b) to assess the potential of the 3D-scanner to detect lesions (benign and malignant) in the breast and
c) to assess the potential to determine the localization of lesions in the breast relative to skin, nipple, and axilla.

Study design

Patients with abnormalities in the breast at conventional 2D ultrasound will be asked to participate in the study. A 3D-cup ultrasound examination of both breasts will be made. After reconstruction of the 3D images, image quality, visualization of anatomic landmarks in the breasts will be assessed and the presence of lesions will be recorded. The images will be compared with the conventional 2D-examination.

Study burden and risks

Ultrasound of the breast is harmless with little discomfort for the patients. The only difference for the patients is that 3D is performed in the prone position and 2D in supine position.
In the cupidus-3D protocol the patient has to remain in prone position for 20 min on a table with her breast hanging in a cup (10 minutes per breast).

Contacts

Public
Philips Research

High Tech Campus 34
5656 AE Eindhoven
Nederland
Scientific
Philips Research

High Tech Campus 34
5656 AE Eindhoven
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

All women who undergo a medically indicated diagnostic breast ultrasound examination with at least one focal mass are eligible for this study.

Exclusion criteria

Age <18 years
Unwilling or unable to give informed consent
Breast size too large to fit in the cup
Not able to tolerate prone posture (neck or back problems)
Breast implants
Breast piercing
non-focal disease processes (e.g. mastitis)

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2007
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL18222.058.07