How do very low dose images in digital mammography compare to regular dose images? A *proof-of-principle* study on diagnostic performance and physical image quality.

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To investigate the clinical diagnostic performance of (extremely) low-dose views in standard digital mammography and relate this to physical image quality measures.

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

Summary

ID

NL-OMON34375

Source
ToetsingOnline

Brief title
Dose reduction in digital mammography

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
Breast cancer, carcinoma of the breast

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Pink Ribbon en NutsOhra (subsidie aangevraagd;besluit verwacht in juni)

Intervention

Keyword: Breast cancer, Diagnostics, Dose reduction, Mammography

Outcome measures

Primary outcome

Pathology detection, diagnostic quality (subjective), image quality (objective)

Secondary outcome

Lesion type, BIRADS category, need for additional imaging, image noise

Study description

Background summary

An increasing number of women undergo an also increasing amount of mammographic examinations for varying purposes. However, every mammogram adds to a woman*s life-time radiation exposure with subsequent risks.
Due to the possibilities of tailored image processing in digital mammography, reducing radiation dosage, while preserving diagnostic performance, is more realistic than ever before. Thus far only phantom studies have been performed in this field and the relationship between physical image quality measures and diagnostic performance is poorly understood.
Outcomes of our pilot study with mastectomy specimens suggest a possible 80% dose reduction in mammographic images in real practice. We therefore hypothesise that performing digital mammography with only a full radiation dose mediolateral oblique (MLO) view and all additional views obtained with a markedly reduced dose will not significantly affect the diagnostic accuracy. Obtaining low-dose images in addition to a high-dose MLO decreases life-time exposure to radiation and might contribute to breast cancer detection by lowering the threshold for obtaining additional images in the diagnostic as well as the screening setting.

Study objective

To investigate the clinical diagnostic performance of (extremely) low-dose views in standard digital mammography and relate this to physical image quality measures.

Study design

We propose an observational performance (proof-of-principle) study in the hospital setting. In addition to a standard clinical mammogram (MLO and craniocaudal (CC) view) a low-dose CC-view will be performed. Both exam combinations (MLO & low-dose CC, and MLO & full dose CC) will be interpreted independently by three experienced radiologists. Differences in clinical outcome will be analysed in order to determine the diagnostic performance of low-dose CC images in digital mammography. These clinical results will further be related to objective physico-technical measurements of image quality.

Study burden and risks

There is no direct risk in participating, since it encompasses a known and standardised diagnostic procedure. However, the extended procedure does come with lengthening of breast compression time and possible physical discomfort. Since a markedly reduced dose is used for the additional study images associated indirect (stochastic) effects of additional radiation images might be negligible.
Analysing the potential of radiation reduction in a widely and frequently used procedure such as mammography may benefit the entire female population, and therefore the participant as well in case of future mammography examinations.

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, scheduled mammography, age > 30 years, every clinical indication, every ethnicity

Exclusion criteria

no informed consent, male, age < 30 years, pregnancy, lactation, extreme mastodynia, physical conditions that restrict the mammographic assessment (e.g. paralysis, stiffness)

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-10-2010
Enrollment:	400

Type:	Actual

Ethics review

Approved WMO Date:	19-05-2010
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	NL32234.008.10