Marked radiation reduction in mammography investigated.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON27999

Source
Nationaal Trial Register

Brief title
DOSE TRIAL

Health condition

Breast cancer, digital mammography, dosimetry
Borstkanker, digitale mammografie, dosimetrie

Sponsors and support

Primary sponsor: Landelijk ReferentieCentrum voor Bevolkingsonderzoek (LRCB)
Landelijk ReferentieCentrum voor Bevolkingsonderzoek (LRCB)
Postbus 6873
6503 GJ Nijmegen
024-3655155
Source(s) of monetary or material Support: NutsOhra

Intervention

Outcome measures

Primary outcome

1. Detection rate;

2. Subjective diagnostic quality (by radiologists);

3. Image quality (by physico-technical methods).

Secondary outcome

1. Image noise (by radiologists);

2. BIRADS category;

3. Need for additional imaging;

4. Lesion type (in case of visible pathology).

Study description

Background summary

Rationale:

With the incidence of breast cancer still rising we see an increasing number of women, irrespective of age, undergo an also increasing amount of mammographic examinations for varying purposes. However, mammography is associated with ionising radiation and 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 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 of digital mammography.
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.

Objective:

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

1. To determine the effect of low dose images on the subjective rating of image quality and diagnostic performance by a number of independent radiologists;

2. To quantify image quality of low-dose and standard dose views in digital mammography using physico-technical methods;

3. To relate this information to results from technical quality control measurements.

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 population:

Women older than 30 years having mammography performed in our hospital (St. Elisabeth), irrespective of medical complaints or history.

Main study parameters/endpoints:

Primary: Pathology detection, diagnostic quality (subjective), image quality (objective).

Secondary: Lesion type, BIRADS category, need for additional imaging, image noise.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

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.

Study objective

Performing 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 of digital mammography.

Study design

All results are to be expected in one year.

Intervention

Additional low-dose mammographic views.

Contacts

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Eligibility criteria

Inclusion criteria

1. Female;

2. Age > 30 years;

3. Scheduled mammography;

4. Every clinical indication;

5. Every ethnicity.

Exclusion criteria

1. No informed consent;

2. Male;

3. Age < 30 years;

4. Pregnancy;

5. Lactation;

6. Extreme mastodynia (breast pain);

7. Physical conditions that restrict mammography assessment (e.g. paralysis, stiffness, etc.).

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

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

Ethics review

Positive opinion

Date:	12-01-2011
Application type:	First submission

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
NTR-new	NL2296
NTR-old	NTR2687
Other	METC Elisabeth ZHS / CCMO : 1019 / NL32234.008.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A