The cost effectiveness of preselection for non-invasive pre-assessment of women referred to full hospital assessment on the basis of a positive screening examination for breast cancer, compared to the current practice.

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON32713

Source
ToetsingOnline

Brief title
MASS (Modified Assessment of referred women in Service Screening)

Condition

- Other condition

Synonym
breast cancer, Mamma carcinoma

Health condition

Borstkanker

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Breast-cancer, cost-effectiveness, screening

Outcome measures

Primary outcome

The main outcome parameter is the negative predictive value of preselection, which is interrelated to secondary outcome parameters such as hospital referral rate, detection rate, false-positive rate and the ultimate outcome survival (estimated through a microsimulation model).

Secondary outcome

Additional outcome parameters are quality of life, anxiety, satisfaction, productivity losses, patient time costs and volumes of care. The cost-effectiveness analysis will estimate the cost per QALY gained and cost per percentage increase in satisfaction with screening, or, if effects differ, the incremental cost per QALY gained as the long run modelling outcome.

Study description

Background summary

Evaluation of the Dutch breast cancer screening programme showed that the number of cancers detected could be increased by increasing the referral rate. However, this would lead to a corresponding increase of false-positives, resulting in an increased workload for GPs and hospital specialists, additional

financial costs and increased patient anxiety.

Study objective

Our objective is to study the efficiency of a modified assessment strategy which will counter the negative consequences of an increased referral rate.

Study design

The study adopts a randomized clinical trial design with randomization before consent.

Intervention

Women who are randomized into the intervention group that are assessed with a BI-RADS code 4 or 5 (suspicious for malignancy) will directly be referred to full hospital assessment, as in current screening practice. Non-invasive pre-assessment will not be sufficient to reach a decision on diagnosis. Women who are randomized into the intervention group with a BI-RADS code 0 (more information needed) will be referred to non-invasive pre-assessment in the screening setting. The pre-assessment consists of an additional mammogram and/or a breast ultrasound. The results of pre-assessment will either: increase the suspicion that a malignant lesion is present (upgrade to BI-RADS 3, 4, 5), in which case the woman will be referred for full hospital assessment; or virtually exclude this possibility (downgrade to BI-RADS 1, 2), in which case the woman will be classified as *definite benign* and go home reassured.

Study burden and risks

Women who participate in the study have to pay one extra visit to the pre-assessment centre. In addition, the women are requested to fill in a questionnaire that measures the quality of life, psychological consequences of an abnormal screening mammography and satisfaction. A representative sample of 200 women in both arms is requested to fill a diary to register the use of volumes of care, productivity losses and costs. The intervention is not a treatment. It does not differ from the current practice in the type of diagnostic techniques. It only differs in the workflow. Therefore, the risks are negligible.

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

All women referred to hospital on basis of a positive screening mammography.

Exclusion criteria

Women who don*t understand the Dutch language, as well as women who are in a state of diminished responsibility or mentally disabled. they are not able to fill in the questionnaire and will not understand the information provided by the research assistant. They are therefore excluded.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	23-10-2009
Enrollment:	4568
Type:	Actual

Ethics review

Approved WMO

Date:	25-06-2009
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	NL25266.091.08
Other	nummer NTR 1480