PRISMA study: Personalised RISk-based MAmmascreening

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Objective 1: To collect information on risk factors and biomarkers in a screening cohort, develop a tailor-made risk prediction model and, subsequently, model the impact of adapting breast cancer screening policy to populations at varying levels of...

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

Summary

ID

NL-OMON44455

Source
ToetsingOnline

Brief title
PRISMA study

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
breast cancer; mamma carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Health Evidence
Source(s) of monetary or material Support: ZonMw

Intervention

Keyword: Breast neoplasms, Mammography, Mass screening, Risk factors.

Outcome measures

Primary outcome

Since the purpose of this study is developing a risk prediction model for breast cancer, there is no primary study parameter as such. Measures to compare the current risk prediction models and the newly developed models will be the Area under the Receiver Operator Characteristic curve (AUCROC), decision analytic measures, like the Net Reclassification Improvement (NRI), and the Integrated Discrimination Improvement (IDI).

Secondary outcome

We will use the well-establised MISCAN model to assess the cost-effectiveness of the most promising risk-based screening scenarios.

Study description

Background summary

In most EU-countries, women in a specific age group are invited for breast cancer screening. This *one-size-fits-all* screening approach, based only on age, fails to take advantage of the growing ability to predict individual variation in risk of breast cancer and to translate that information into better screening outcomes. The PRISMA study (Personalised RISk-based MAmmascreening) will focus on how to make screening for breast cancer more effective and efficient by targeting women who are most likely to benefit and reducing exposure to screening in those women who are more likely to experience the harms. Potential implementation of this new approach presents a number of major challenges. One includes the acceptability for women in the target population. Furthermore, extending the personalised paradigm to the field of breast cancer screening will raise additional questions with respect to medico-legal and ethical considerations.

Study objective

Objective 1: To collect information on risk factors and biomarkers in a screening cohort, develop a tailor-made risk prediction model and, subsequently, model the impact of adapting breast cancer screening policy to populations at varying levels of risk, i.e. to assess whether moving from the current *one-size-fits-all* screening policy to more personalised risk-based screening regimens can optimise the efficacy of breast cancer screening using the same resources.

Objective 2: To make an inventory on communication, medico-legal and ethical considerations related to personalised risk-based screening and present a synthesis at an interdisciplinary expert meeting, along with results of the project, in order to discuss implications and recommendations for current vs personalised risk-based screening policies.

Study design

Observational cohort study.

Study burden and risks

Participants will be asked to complete a web-based questionnaire on currently established risk factors for breast cancer. Breast density will be automatically assessed on the unprocessed screening mammograms. For a part of the study population, the study includes donating blood samples one time (2 x 10 ml; 2 x 6 ml) in order to determine plasma hormone levels, RNA profiles of blood platelets, other blood markers and to extract DNA for genotyping. A saliva sample (2 ml), instead of a blood sample, will be collected from a small subsample of the population in order to extract DNA. Risks associated with participation are confined to the normal risks of taking blood samples (risk of fainting and of bruising). Since the drawing of blood will be done by professionals, risks are low. In the mobile screening units, women will first be asked to complete the online questionnaire and give consent to the analysis of their unprocessed mammogram. They are also asked if they consent to the PRISMA-team contacting them in case they are diagnosed with breast cancer in the future. If women consent to this, they will be asked to provide either a blood or saliva sample after the breast cancer diagnosis. Since a breast cancer diagnosis indicates a tumultuous time for the woman, a saliva sample could be a less invasive alternative.

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 invited for breast cancer screening
- Able to communicate in Dutch
- Able to read and understand the participant information and informed consent form

Exclusion criteria

- Women who cannot make the decision to participate by themselves (mentally ill or mentally handicapped)
- Not able to fill out a web-based questionnaire

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-09-2014
Enrollment:	90000
Type:	Actual

Ethics review

Approved WMO Date:	25-06-2014
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	08-10-2015
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	01-08-2016
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	10-01-2017
Application type:	Amendment
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	NL48239.091.14