Can we use breast density measurement to indicate whether mammography or MRI can best be used to screen women with familial risk for breast cancer?

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28552

Source
Nationaal Trial Register

Brief title
FaMRIsc

Health condition

Breast Cancer, Neoplasm Mammae, Screening, MRI, Mammography, Breast Density
Borst kanker, Neoplasma Mammae, Screening, MRI, mammografie, borstdensiteit

Sponsors and support

Primary sponsor: Erasmus MC, Daniel den Hoed Clinic, Faculty of Medicine, Department of Surgical Oncology
Source(s) of monetary or material Support: Dutch Cancer Society (KWF) EMCR 2009-4491, ZonMw 200320002

Intervention

Outcome measures

Primary outcome

The number of tumours detected at screening examinations and in between screening examinations (interval tumours), and the stage distribution at diagnosis in the different trial arms. The results will also be analyzed by density score.

Secondary outcome

Sensitivity, proportion of false-positive results and specificity of MRI and mammography in both arms. Furthermore breast cancer mortality reduction will be estimated using breast cancer microsimulation models (MISCAN). Cost effectiveness analyses will be performed. Costs will be calculated per quality adjusted life-year gained.

Study description

Background summary

Twenty-five percent of all breast cancers are detected before age 50 years. A positive family history is a major risk factor for breast cancer at a young age. In over 75% of the families that display clear clustering of breast cancer no causative mutation in the BRCA1, the BRCA2 or other genes can be detected. Women from these families cannot be tested to distinguish those with high from those with average risk of developing breast cancer.

Tumour stage at detection is of key influence on survival. Therefore Dutch guidelines advise regular breast surveillance to all women with a family history. For women with an estimated cumulative lifetime risk (CLTR) ≥20% yearly mammography between 40 and 50 years is advised. Yearly mammography and specialist clinical examination is advised for women with CLTR ≥30% between 35 and 60 years. Although due to screening tumours might be found at a more favourable tumour stage, screening also causes false-positive test results.

In the last decade several screening trials have been completed and MRI had a significant higher sensitivity than mammography in all studies. However in most studies MRI gave significantly more false-positive results and mammography had better sensitivity for Ductal Carcinoma in Situ (DCIS). Nevertheless for BRCA1/2 mutation carriers, who have a CLTR of 40-70%, screening with yearly MRI has been shown cost-effective.

For the larger group of women with familial risk, but without a proven BRCA1/2 mutation it is not clear whether additional MRI is advantageous for some: no separate cost-effectiveness results have been published yet. Since previous screening studies have performed MRI and mammography simultaneously the difference in stage of the tumours when detected by mammography alone is not known. A randomized controlled trial is needed therefore.
Apart from family history and age high density of the breast tissue is the best documented

and most important risk factor for breast cancer. Breast density may also strongly influence screening-results:

1. It increases breast cancer incidence significantly, but;

2. Decreases the sensitivity of mammography, though not of MRI, while;

3. False-positive findings at mammography may increase.

High breast density is prevalent in 60% of women below age 50.

Breast density may be the best predictor whether a woman with high familial breast cancer risk can be screened most effectively with mammography or MRI. If proven, breast density measurement can be used to apply the most effective screening tool to screen women with increased risk for breast cancer.

Study objective

A proportion of women with high familial breast cancer risk can be screened most effectively with MRI. Breast density may be the best predictor whether to screen this particular group of women with mammography or MRI.

Study design

N/A

Intervention

1. MRI with clinical examination yearly + mammography every other year (year 1 + 3) (n=1000;

2. Mammography with clinical examination yearly (n=1000).

Contacts

Public
Erasmus MC, Daniel den Hoed Clinic, Faculty of Medicine, Department of Surgical Oncology, Groene Hilledijk 301
S. Saadatmand
Rotterdam 3075 EA
The Netherlands
+31 (0)10 7041223

Scientific
Erasmus MC, Daniel den Hoed Clinic, Faculty of Medicine, Department of Surgical Oncology, Groene Hilledijk 301
S. Saadatmand
Rotterdam 3075 EA
The Netherlands
+31 (0)10 7041223

Eligibility criteria

Inclusion criteria

1. Cumulative Life Time Risk ≥20%, defined by Claus Adjusted Tables;

2. Age at inclusion 30-55 years, or 5 years younger than youngest case of breast cancer in family;

3. Willing to provide informed consent.

Exclusion criteria

1. Personal history of invasive (breast) cancer, except for basal cell carcinoma;

2. Having a (50% risk of a) known BRCA1, BRCA2 or P53 mutation;

3. Breast MRI contra-indications like kidney dysfunction or metal implantation.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-01-2011
Enrollment:	2000
Type:	Anticipated

Ethics review

Positive opinion

Date:	03-03-2011
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	NL2661
NTR-old	NTR2789
Other	KWF EMCR / ZonMw / MEC Erasmus MC : 2009-4491 / 200320002 / 2010-292;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A