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?

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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.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28552

Bron
NTR

Verkorte titel
FaMRIsc

Aandoening

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

Ondersteuning

Primaire sponsor: Erasmus MC, Daniel den Hoed Clinic, Faculty of Medicine, Department of Surgical Oncology
Overige ondersteuning: Dutch Cancer Society (KWF) EMCR 2009-4491, ZonMw 200320002

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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

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

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	15-01-2011
Aantal proefpersonen:	2000
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	03-03-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2661
NTR-old	NTR2789
Ander register	KWF EMCR / ZonMw / MEC Erasmus MC : 2009-4491 / 200320002 / 2010-292;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A