# The added value of multivoxel MR spectroscopy in young women with a high risk for breast cancer

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|---|---|
| **Ethische beoordeling** | Niet van toepassing |
| **Status** | Werving nog niet gestart |
| **Type aandoening** | - |
| **Onderzoekstype** | Observationeel onderzoek, zonder invasieve metingen |

## Samenvatting

### ID

NL-OMON25637

**Bron**
Nationaal Trial Register

**Verkorte titel**
BRESPECT

**Aandoening**

breast cancer

### Ondersteuning

**Primaire sponsor:** UMCG
**Overige ondersteuning:** Pink Ribbon

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

**Primaire uitkomstmaten**

To determine the added value of multivoxel MRS in equivocal breast lesions detected through screening with DCE-MRI. This study will especially focus on young women with a high risk of breast cancer.<br>
The hypothesis is that with the application of a DCE-MRI scan with quantitative multivoxel MRS, 23% of the number of false positive breast lesions and related to that, the number of unnecessary invasive procedures, will be prevented as compared to a regular DCE-MRI.

# Toelichting onderzoek

### Achtergrond van het onderzoek

Mammography and dynamic contrast-enhanced Magnetic Resonance Imaging (DCE-MRI) are used as standard modalities for breast cancer screening in the (genetically) high risk women. DCE-MRI has the highest overall negative predictive value (NPV) of all imaging techniques and is therefore able to safely exclude malignancy (NPV > 98%) (7, 8). The problem with DCE-MRI is that enhancement patterns show considerable overlap in malignant and benign breast lesions. Therefore, the majority of the enhanced breast lesions are considered equivocal. Therefore, women may be exposed to uncertainty about outcomes of the screening irrespective of the modality used, resulting in anxiety. A substantial amount of these women will undergo unnecessary invasive procedures in case of an equivocal lesion. Ultrasound-guided biopsy (core needle biopsy) is discomforting and is sometimes accompanied by complications, such as hematomas.

The purpose of the study is to determine the added value of multivoxel MRS in women with increased risk for breast cancer and equivocal enhanced breast lesions detected at screening with standard Dynamic Contrast Enhanced Magnetic Resonance Imaging (DCE-MRI). Thereby, to decrease the number of false positive breast lesions on DCE-MRI scans with multivoxel MR spectroscopy (MRS) and to prevent unnecessary invasive procedures or unnecessary extended breast surgery.

### Doel van het onderzoek

The purpose of the study, therefore, is to determine the added value of multivoxel MRS in equivocal breast lesions detected through screening with DCE-MRI. This study will especially focus on young women with a high risk of breast cancer.
The hypothesis is that with the application of a DCE-MRI scan with quantitative multivoxel MRS, 23% of the number of false positive breast lesions and related to that, the number of unnecessary invasive procedures, will be prevented as compared to a regular DCE-MRI.

The expectation is that women prefer the new non-invasive diagnostic work-up instead of the biopsy, and that this, when implemented in clinical practice will improve the quality of life of the women involved.

### Onderzoeksopzet

T0: Suspect breast lesion on MRI

T1: Multivoxel MR spectroscopy

(same day) Breast core needle biopsy

T2: (within one week) Results of MMR spectroscopy and CNB

**Onderzoeksproduct en/of interventie**

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# Contactpersonen

## Publiek

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## Wetenschappelijk

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# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in this study, a subject must meet all of the following

criteria: participation in a screening programme for a BRCA1 or BRCA2 gene mutation carrier, or other genetic predisposing with a markedly increased risk of breast cancer, such as untested first degree relativea of a gene mutation carrier, family history consistent with hereditary breast cancer, estimated personal lifetime breast cancer risk ¡Ý 25% or prior radiation therapy to the chest below age 40

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential subject who meets any of the following criteria will be excluded from participation in this study: breast hematoma or bilateral breast implants.

## Onderzoeksopzet

### Opzet

| | |
|---|---|
| Type: | Observationeel onderzoek, zonder invasieve metingen |
| Onderzoeksmodel: | Anders |
| Toewijzing: | N.v.t. / één studie arm |
| Blindering: | Open / niet geblindeerd |
| Controle: | N.v.t. / onbekend |

### Deelname

Nederland

| | |
|---|---|
| Status: | Werving nog niet gestart |
| (Verwachte) startdatum: | 01-11-2016 |
| Aantal proefpersonen: | 77 |
| Type: | Verwachte startdatum |

## Ethische beoordeling

Niet van toepassing

| | |
|---|---|
| Soort: | Niet van toepassing |

# Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 43211
Bron: ToetsingOnline
Titel:

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

| Register | ID |
|---|---|
| NTR-new | NL6040 |
| NTR-old | NTR6171 |
| CCMO | NL58550.042.16 |
| OMON | NL-OMON43211 |

# Resultaten

**Samenvatting resultaten**
Sijens PE, Dorrius MD, Kappert P, Baron P, Pijnappel RM, Oudkerk M. Quantitative multivoxel proton chemical shift imaging of the breast. Magn Reson Imaging. 2010 Apr; 28(3):314-9. doi: 10.1016/j.mri.2009.11.004. Epub 2010 Jan 13.<br>
Dorrius MD, Pijnappel RM, Jansen-van der Weide MC, Jansen L, Kappert P, Oudkerk M, Sijens PE. Determination of choline concentration in breast lesions: quantitative multivoxel proton MR spectroscopy as a promising noninvasive assessment tool to exclude benign lesions Radiology 2011 Jun;259(3):695-703. doi: 10.1148/radiol.11101855. Epub 2011 Apr 1.
Dorrius MD, Pijnappel RM, van der Weide Jansen MC, Jansen L, Kappert P, Oudkerk M, Sijens PE. The added value of quantitative multi-voxel MR spectroscopy in breast magnetic resonance imaging.Eur Radiol. 2012 Apr; 22(4):915-22. doi: 10.1007/s00330-011-2322-0. Epub 2011 Nov 11.>