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

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

Summary

ID

NL-OMON43211

Source
ToetsingOnline

Brief title
BRESPECT

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
breast cancer, breast carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Pink Ribbon

Intervention

Keyword: Breast cancer, High risk, MRI, Spectroscopy

Outcome measures

Primary outcome

Mulitvoxel MRS can differentiate between benign and malignant breast lesions in equivocal enhancing lesions on the DCE-MRI. Unnecessary biopsy can be prevented in case of a benign lesion. When a woman has proven breast cancer and more enhancing breast lesions are present in the same breast (or contralateral breast) which are benign, unnecessary extended breast surgery can be prevented with multivoxel MRS and thereby overtreatment.

Secondary outcome

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.

Study description

Background summary

Dynamic contrast enhanced breast MRI has the highest overall negative predictive value (NPV) of all imaging techniques and is therefore able to safely exclude malignancy (NPV > 98%). 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. . A substantial amount of these women will undergo unnecessary invasive procedures in case of an equivocal lesion.
Multivoxel MRS, performed according to the protocol of Sijens et al. (Sijens 2010), is a non-invasive technique that can provide tumor metabolic information. The diagnostic value of MRS is generally based on the detection of elevated levels of choline containing compounds. From the multivoxel MRS scan, the mean and highest choline concentration within each equivocal enhancing

breast lesion is calculated. A threshold of 1.5 mM is used to differentiate between benign and malignant breast lesions. In recent publications no overlap of the highest choline concentration was found between benign and malignant breast lesions. Breast lesions with the highest choline concentration <= 1.5mM were benign and breast lesions with the highest choline concentration >= 1.7 mM were malignant (Dorrius 2011).

Study objective

The purpose of the study is to determine the added value of multivoxel Magnetic Resonance Spectroscopy (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). The second aim is to assess whether or not women prefer this new diagnostic modality.

Study design

In this prospective consecutive study 77 women with an enhancing breast lesion classified as BIRADS >= 3 and a size of >= 0.8 cm on DCE-MRI will be included.MR scans are performed at a 3.0T system using a whole body MR scanner with a dedicated bilateral breast coil. Women will undergo the standard MRI protocol (T2 weighted image and dynamic T1 weighted images with I.V. contrast medium and diffusion weighted imaging (DWI)) for screening in prone position. In case an enhanced breast lesion is assessed as BIRADS >=3 and the lesion is >= 0.8 cm, the woman will return to the hospital for the standard work-up (target ultrasound and if visible on ultrasound followed by ultrasound guided biopsy). Prior to the standard work-up a multivoxel MRS will be made. This is a MRI sequence without I.V. contrast and has a duration of approximately 20 minutes (protocol of Sijens et al 2010). Histopathology or 6 months follow-up DCE-MRI is set as the regular follow-up in this study. A questionnaire will be used to assess whether women prefer the new diagnostic modality or biopsy.

Study burden and risks

Until now, no hazardous effects of the MRI are documented. The burden for the patient is an extra MRI scan of 20 minutes and filling out a questionairre. However these patients are familiar with a MRI scan, because they undergo a screenings MRI scan every year.

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

Seventy-seven women with a solid breast lesion >= 0.8cm and BIRADS classification >= 3 on the MRI will be consecutively enrolled into the study
Inclusion 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 >= 25% or prior radiation therapy to the chest below age 40.

Exclusion criteria

breast hematoma or bilateral breast implants.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-11-2017
Enrollment:	77
Type:	Actual

Ethics review

Approved WMO Date:	24-05-2017
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	13-09-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 25637
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL58550.042.16
Other	volgt