A new diagnostic development in MRI screening for breast cancer

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Primary objective:To compare the specificity of multiple voxel MR spectroscopy with MRI.Secondary objective: To decrease the number of false positive diagnostic outcomes by using multiple-voxel MR-spectroscopy and therefore to reduce benign biopsies...

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

Summary

ID

NL-OMON33969

Source
ToetsingOnline

Brief title
CSI in breast cancer

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
breast cancer, mamma carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: breast cancer, Chemical Shift Imaging (CSI), MR spectroscopy, MRI

Outcome measures

Primary outcome

To compare the specificity of the multiple-voxel MR spectroscopy with the

standard MRI and

as second main aim a reduction of the number of false-positive diagnostic

outcomes.

Sensitivity, specificity, positive predictive value, negative predictive value

and 95% CI will be calculated.

Secondary outcome

No applicable

Study description

Background summary

The worldwide incidence of carcinoma of the breast is higher than other malignancies among women.
Breast cancer screening is one of the possibilities to reduce breast cancer mortality.While mammography
is the standard breast cancer screening exam, screening with MRI is more effective for genetic high risk
patients or for women with dense breast tissue. MRI is able to detect early stage breast malignancy
which is occult to clinical examination and conventional imaging. The overall sensitivity of MRI usually
exceeds 90%. The overall specificity of MRI in discriminating malignant from benign has been variable
ranging from 37% to 97%, resulting in a considerable number of benign biopsy outcomes. Therefore,
it is very important to develop new techniques to increase the specificity of MRI aiming at a reduction of

the number of invasive diagnostic procedures on MRI. A promising approach to clarify the precise nature
of a lesion is MR spectroscopy.MR spectroscopy can demonstrate metabolic differences between tumors
and normal tissues. The diagnostic value of 1H MR spectroscopy is typically based on the detection of
elevated levels of choline (Cho) compounds, which are a marker of an active malignant tumor. In prior
studies of single-voxel 1H MR spectroscopy performed with 1.5 T MR units specificity of 85% (range,
67%-100%) has been reported. The single-voxel technique has limitations in terms of lesion coverage,
which may effect the sensitivity of Cho detection due tumor heterogeneity. Multiple-voxel technique or
chemical-shift imaging (CSI) may be used to acquire spectroscopic information from multiple voxels over
a large volume of interest in single measurement, and hence is suitable for analyzing the regional
distribution of tumor metabolites. Although it is commonly used in the brain and prostate, only two
studies with breast lesions have been reported. Beak et al. showed that the metabolic information
measured by CSI may be used for improving specificity in the diagnosis of breast cancer in 36 patients.
Also CSI may provide advantages over the single-voxel technique for characterizations of breast lesions.
Further investigations in larger studies are needed.

Study objective

Primary objective:To compare the specificity of multiple voxel MR spectroscopy with MRI.
Secondary objective: To decrease the number of false positive diagnostic outcomes by
using multiple-voxel MR-spectroscopy and therefore to reduce benign biopsies.

Study design

Clinical, observational study: to assess whether multiple-voxel MR spectroscopy increases the specificity
of the MRI. Pathology is used as gold standard. Thirty patients with a solid breast lesion >= 1cm and
BIRADS classification 3 of 4 on the mammogram will undergo MRI and MR spectroscopy (in one setting).
Appoximately half of the lesions will be malignant if fifteen breast lesions with BIRADS 3 and fifteen breast

lesions with BIRADS 4 will be included. This is based on the outcome of all breast MR scans which have been
made in UMCG in 2006.
The patients will undergo a standard MRI with contrast agent (gadolinium), which takes 25 minutes.
MR spectroscopy will be performed after the breast lesion is detected by MRI, which will also take
15 minutes. The acquired raw MR spectroscopy data will be transferred to a computer workstation
and elevated levels of choline compounds will be measured.

Study burden and risks

Until now, no hazardous effects of the MRI are documented. MRI is contra-indicated in patients with
non-MR compatible implant, disorder of the kidney function and claustrophobia. The contrast agent
used with MR examinations, Gadoterate megluine, is considered very safe, and has been used in
clinical practice for many years. In some cases nausea (1-2%) or hives (<1%) can occur. Very rarely an
anaphylactoid reaction can occur. The burden for the patient is one extra visit to the hospital for the
MRI scan and the possibility of finding extra suspect lesions with MRI.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
9700 RB Groningen
Nederland
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1
9700 RB Groningen
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

solid breast lesion >= 1cm
BIRADS classification 3 or 4 on the mammogram.
Patients are >= 18 years

Exclusion criteria

history of breast cancer
breast hematoma
protheses
claustrophobia
non-MR compatible implants
disorder of kidney function

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending

Start date (anticipated):	01-03-2009
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO Application type:	First submission
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

No registrations found.

In other registers

Register	ID
CCMO	NL23363.042.09