Image quality of MR-Imaging on the MR-High Intensity Focused Ultrasound breast system

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Primary objectivesWhat is the quality of MR images acquired on the MR-HIFU breast system in volunteers and patients with a fibroadenoma relative to the quality of MR images acquired on a conventional diagnostic 3-Tesla MRI scanner? We will assess...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Breast neoplasms benign (incl nipple)
Study type	Observational invasive

Summary

ID

NL-OMON36389

Source
ToetsingOnline

Brief title
Imaging on the MR-HIFU breast system

Condition

- Breast neoplasms benign (incl nipple)

Synonym
benign tumor originating from glandular tissue, fibroadenoma

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Center for Translation Molecular Medicine (CTMM)

Intervention

Keyword: breast, HIFU, Image quality, MRI

Outcome measures

Primary outcome

The main study endpoints are:

- image quality --> assessed by a score based on delineation of anatomical structures, contrasts, SNR and artefacts of both MRI scans.

- lesion descriptors of the BI-RADS lexicon in patients with a fibroadenoma --> described by shape and margin of the lesion and other findings on the MRI scans (e.g. edema, lymphadenopathy, skin thickening).

Secondary outcome

Secondary study endpoints

- geometric deformation in breasts with different sizes --> assessed by overlaying the two MRI scans and assess whether there is deformation and assess the variety of deformation in breasts with different sizes.

- size of fibroadenoma --> assessed by scoring the maximum diameter of the fibroadenoma in 3 orthogonal planes (MaxTrans, MaxSag, MaxCor) on both MRI scans.

- relative position of the fibroadenoma --> assessed by measuring the shortest distance from the fibroadenoma to the musculus pectoralis, the chest wall and the skin in 3 orthogonal planes (MaxTrans, MaxSag, MaxCor) on both MRI scans.

Study description

Background summary

Breast cancer is the most frequently occurring malignant disease in women worldwide, comprising 16% of all female cancers2. Nowadays, breast conserving therapy is standard of care for patients with localized breast cancer1.
However, there is growing interest in less invasive treatment techniques, such as radiofrequency ablation, laser ablation and cryoablation. Another new and completely non-invasive treatment modality is Magnetic Resonance guided High Intensity Focused Ultrasound3, 4. With this technique, a focused ultrasound beam is used to thermally ablate tissue, while MRI is employed to aim the ultrasound focus on the lesion and for continuously measuring temperature maps to ensure optimal safety. Breast lesions are considered especially suited for treatment with MR-HIFU due to clear visualization of breast lesions with MRI and the peripheral location of the breast which allows safe targeting.
Philips Healthcare developed a dedicated breast system for thermal ablation of lesions in the breast. The system consists of a table top which houses multiple HIFU transducer arrays and a RF receive coil. The system was designed to dock on top of a standard 1.5-T MRI scanner. Recently, a prototype of this system was installed in the UMC Utrecht.
Patients will lie prone on the tabletop of the breast system with the target breast hanging in a cup filled with water. The breast cup is filled with water to enable ultrasound waves to enter the breast without reflection. Previous studies have shown that MR-HIFU is feasible and safe in patients with breast cancer5-9. However, non of these studies included a large number of patients and complete necrosis was achieved in only 20-50% of patients.
The Philips MR-HIFU breast system differs from the systems previously used for breast tumor ablation. Eight separate transducers are circumferentially positioned around the breast cup. This method of lateral sonication reduces the risk of heating heart and lungs, and the wide aperture of the transducer reduces the risk of skin heating. The MR-HIFU breast system uses a volumetric ablation method, which can induce larger and more homogeneous ablation volumes per sonication and a reduction in treatment time. This is why we think we can achieve better results than previous studies using other systems.
Our final goal is to treat patients with breast cancer using the MR-HIFU breast system, but we have to go through several steps before we can start with MR-HIFU ablation in patients with breast cancer. First, it is very important to assess the quality of images acquired on the MR-HIFU system. This is necessary since the integration of the HIFU transducer into the MR table top made it necessary to develop a new RF receive coil with different imaging capacities from the coils normally used for breast MRI.
In a second study, we are going to compare image quality and lesion characteristics between a CE-MRI on the MR-HIFU breast system and a conventional 3-Tesla CE-MRI in patients with breast cancer.
In a third study, we intend to start MR-HIFU ablation in patients with symptomatic fibroadenomas to assess the accuracy and safety of the MR-HIFU breast system.

Ultimately, we plan to perform MR-HIFU ablation in patients with breast cancers to assess the efficacy of the MR-HIFU breast system in a treat-and-resect study.
The current protocol aims on the assessment of the quality of MR-imaging on the MR-HIFU breast system in healthy volunteers and in patients with a fibroadenoma relative to the quality of MR-imaging on a conventional diagnostic MRI scanner. We chose to start with imaging of volunteers, because no imaging of human beings has been done on the Philips MR-HIFU breast system with the water box filled with water. We focus on quality of MR-imaging on the MR-HIFU breast system in patients with fibroadenomas, because this will be the first cohort of patients we intend to treat with MR-HIFU. Fibroadenomas are benign tumors in the breast, are visible on a T2-weighted image without the use of a contrast agent, and do not require surgical excision from a medical point of view.

In conclusion, as a first step it is very important to compare quality of images acquired on the MR-HIFU breast system with images acquired on a conventional diagnostic 3-Tesla MRI scanner. In the future, when evaluating patients eligible for treatment with MR-HIFU, patients will always be evaluated based on a conventional diagnostic 3T MRI. Therefore, it is very important to assess differences between the two scans, both in healthy volunteers and in patients with a fibroadenoma.

Study objective

Primary objectives
What is the quality of MR images acquired on the MR-HIFU breast system in volunteers and patients with a fibroadenoma relative to the quality of MR images acquired on a conventional diagnostic 3-Tesla MRI scanner? We will assess the image quality in terms of:
- delineation of anatomical structures such as fibroglandular tissue, fatty tissue and muscles
- contrasts between various anatomical structures
- SNR (signal to noise ratio)
- quantity and variety of artefacts.
What is the quantitative assessment of the lesion according to the Breast MRI-lexicon criteria of the American College of Radiology (ACR) of both MRI scans in patients with a fibroadenoma?

Secondary objectives
What is the geometric deformation of the breast on the MR-HIFU breast system in volunteers and patients with a fibroadenoma relative to the MR images acquired on a diagnostic 3-T MRI scanner and its association with breast size?
What is the size and position of a fibroadenoma in patients on images acquired on the MR-HIFU breast system compared to the size and position on MR images acquired on a 3-T MRI scanner?

Study design

The study is designed as a single-centre, single arm, prospective, cohort study to evaluate the image quality of MR images acquired on the MR-HIFU breast system in volunteers and patients with a fibroadenoma. All volunteers and patients will be included in the University Medical Center Utrecht.

Study burden and risks

Volunteers and patients will undergo MR imaging on the MR-HIFU breast system and on a 3-T MRI scanner, both without the use of a contrast agent. There are no direct benefits for the subjects participating in this research, but the risks are considered minimal.

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

Inclusion criteria for volunteers:
Women
Age >= 18 years
Weight < 80 kg
Physical fitness to lie in the MRI scanner for a maximum duration of 1 hour;Inclusion criteria for patients with fibroadenomas:
Women
Age >= 18 years
Weight < 80 kg
Physical fitness to lie in the MRI scanner for a maximum duration of 1 hour
One or more histological proven fibroadenomas

Exclusion criteria

Exclusion criteria for volunteers and patients with fibroadenomas:
Contra-indications to MRI scanning according to the guidelines of the hospital
Pregnant or lactating women
Volunteers and patients who don*t want to be informed about unexpected findings.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-09-2011
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	3-Tesla MRI scanner and the MR-HIFU breast system;docked on top of a standard 1.5-Tesla MRI scanner
Registration:	No

Ethics review

Approved WMO Date:	19-08-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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: 20705
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL35059.041.11
OMON	NL-OMON20705