Image quality on the MR-HIFU breast system.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20705

Source
NTR

Health condition

Our final goal is to treat patients with breast cancer using the MR-HIFU breast system. Before we can do this, we have to go through several steps. The first step is to assess the quality of images acquired on the MR-HIFU system.

Sponsors and support

Primary sponsor: University Medical Center Utrecht, Department of Radiology
Source(s) of monetary or material Support: Center for Translational Molecular Medicine (CTMM), VOLTA (VOLumetric Thermal Ablation) project

Intervention

Outcome measures

Primary outcome

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

2. 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

1. 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;

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

3. 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 conserving therapy is standard of care for patients with localized breast cancer. Due to technological advances, there is growing interest in less invasive treatment techniques. Magnetic Resonance guided High Intensity Focused Ultrasound (MR-HIFU) is a new and non-invasive treatment modality. Philips Healthcare developed a dedicated MR-HIFU breast system for ablation of tumors in the breast. Since MR images acquired on this new system are used for therapy planning, treatment guidance and evaluation of therapy results, it is important to assess the image quality that can be achieved on the dedicated MR-HIFU breast system.

Study objective

This is a single center, prospective study to assess the quality of the MR images acquired on the MR-HIFU breast system in volunteers and patients with a fibroadenoma, by comparing images acquired on the MR-HIFU breast system with images acquired using comparable imaging techniques on a conventional 3-Tesla MRI scanner.

Study design

Two MRI scans (each with a maximal duration of one hour) during one extra visit to the UMC Utrecht.

Intervention

Two MRI scans: One on the MR-HIFU breast system and one MRI scan in a conventional 3-

Tesla MRI scanner.

Contacts

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Eligibility criteria

Inclusion criteria

Inclusion criteria for volunteers:

1. Women;

2. Age ≥ 18 years;

3. Weight < 80 kg;

4. Physical fitness to lie in the MRI scanner for a maximum duration of 1 hour.

Inclusion criteria for patients with fibroadenomas:

1. Women;

2. Age ≥ 18 years;

3. Weight < 80 kg;

4. Physical fitness to lie in the MRI scanner for a maximum duration of 1 hour;

5. One or more histological proven fibroadenomas.

Exclusion criteria

Exclusion criteria for volunteers and patients with fibroadenomas:

1. Contra-indications for MRI scanning according to the guidelines of the hospital;

2. Pregnant or lactating women;

3. Volunteers and patients who don’t want to be informed about unexpected findings.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2011
Enrollment:	30
Type:	Anticipated

Ethics review

Positive opinion
Date: 30-08-2011
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 36389
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL2904
NTR-old	NTR3050
CCMO	NL35059.041.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON36389

Study results

Summary results
N/A