Image quality on the MR-HIFU breast system.

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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...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20705

Bron
NTR

Aandoening

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.

Ondersteuning

Primaire sponsor: University Medical Center Utrecht, Department of Radiology
Overige ondersteuning: Center for Translational Molecular Medicine (CTMM), VOLTA (VOLumetric Thermal Ablation) project

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2011
Aantal proefpersonen:	30
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	30-08-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 36389
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A