Breast imaging using light and sound.

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Breast cancer is one of the most common forms of female cancer worldwide. There are major limitations to the current imaging techniques that are used for diagnosing breast cancer. There is no single technique that combines an excellent sensitivity…

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON26509

Bron
NTR

Aandoening

Breast cancer

Ondersteuning

Primaire sponsor: Prof. dr. ir. Wiendelt Steenbergen
On behalf of Biomedical Photonic Imaging, University of Twente
Overige ondersteuning: SenterNovem, IOP Photonic Devices: HYMPACT project (IPD083374)
Provincie Overijssel via High Tech Health Farm project Photoacoustic Mammoscopy: Development and early evaluation of a high speed Twente Photoacoustic Mammoscope.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Photoacoustic images will be compared with the outcomes of clinical investigation, conventional imaging and pathology. In the first stage of the study, the photoacoustic images will mainly be used to optimize the measurement and analysis methods. In the second phase

of the study, the images of the BIRADS IV and V lesions will qualitatively be described in order to find photoacoustic markers that are indicative for malignancy. In the third stage of the study, which will have a certain overlap with phase 2, also non-cancerous breast will be investigated for the presence or absence of the photoacoustic malignancy markers.

Toelichting onderzoek

Achtergrond van het onderzoek

Breast cancer is one of the most common forms of female cancers worldwide. Current imaging modalities suffer from some major limitations. This observational diagnostic study investigates the feasibility of photoacoustic mammography in breast cancer imaging. Within a period of two years, up to 100 patients from the Centre of Mammacare of the Medisch Spectrum in Twente will be included in the study based on the grade of suspiciousness of their lesions. Patients that agree on cooperation and sign an informed consent form will undergo a 45 minutes lasting non-invasive imaging procedure of the breast lesion. The photoacoustic images will be compared with the results of conventional imaging (X-ray mammography, ultrasonography and, if applicable, Magnetic Resonance Imaging) and if available with histopathology results.

The main objectives of this study are:

1. To optimize the imaging and analyis methods for the visualization of malignancies;

2. To find the photaocoustic markers that are indicative for the presence of a malignancy;

3. To guide the developments of the further generations of the photoacoustic mammoscope.

Doel van het onderzoek

Breast cancer is one of the most common forms of female cancer worldwide. There are major limitations to the current imaging techniques that are used for diagnosing breast cancer. There is no single technique that combines an excellent sensitivity with a good specificity, an appropriate resolution and a high imaging contrast and that can be used in the complete adult female population. In the last years, researchers from the University of Twente have made progress in the development of a new technique for breast cancer imaging: photoacoustic mammography. This technique combines the high contrast of optical imaging with the good resolution of ultrasound. Besides, the contrast is based on functional processes instead of on morphological tissue changes. The clinical feasibility of photoacoustic mammography has been tested with realistic breast phantoms and in a pilot study. We are now at the stage that more clinical data is needed in order to guide the developments of this technique and to find photoacoustic markers that are indicative for malignancy.

Onderzoeksopzet

The photoacoustic images will be analysed after each measurement. Adaptations to the measurement protocol or slight adaptations with respect to safety and comfort can be applied after each measurement. After each phase, the study will be paused for a few weeks to optimise the imaging and analysis methods.

Onderzoeksproduct en/of interventie

No interventions.

Measurements:

Patients who come to the centre for mammacare with a suspicious breast lesion and who follow the inclusion criteria of the current phase, will be asked for cooperation to the study in between the conventional diagnosis and the ultrasound guided biopsy. If the patient agrees on cooperation and signs an informed consent form, her breast will be imaged with the photoacoustic mammoscope. During the measurement the woman has to lie on the bed in a prone position with her breast pendant through the whole in the bed. The breast will be slightly compressed between a window for laser light illumination and an ultrasound detector array. After careful positioning and defining the region of interest, a scan of about 30 minutes will be made. During the scan the patient and all bystanders wear special laser safety goggles. The energy and beam surface are set such that the total fluence is always below the MPE (maximal permissible exposure) safety guidelines.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Adult women, who come to the Centre for Mammacare with a lesion suspicious for malignancy that, after clinical investigation and anamnesis is classified as a BIRADS IV or V (Phase 1,2) or a BIRADS I or II (phase 3) lesion. In addition, the lesion or suspect must have been deemed as being manifestable in a photoacoustic examination;

2. Patients in good general health that allows them to undergo the examination in a prone position for a period of 45 minutes;

3. Patients who are fully competent to give informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Patients whose physical condition is expected to be insufficient for mounting the examination bed and staying on this bed for 45 minutes without too much discomfort;

2. Patients who had a breast biopsy in 3 months prior to this study;

3. Patients with bloody discharge, ulcers or wounds on the breast;

4. Patients with a history of surgery (including cosmetic surgery) or radiation therapy on the breast within a period of 5 years prior to the study;

5. Patients with breast implants;

6. Patients who currently undergo chemotherapy.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel

Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-12-2010
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	17-06-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2804
NTR-old	NTR2945
Ander register	METC Medisch Spectrum Twente / ABR-CCMO : P10-0001 / NL 30718.044.09;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A