Imaging of the breast using light and sound

No registrations found.

Ethical review	Positive opinion
Status	Other
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON20184

Source
NTR

Brief title
n/a

Health condition

breast cancer
borstkanker

Sponsors and support

Primary sponsor: Prof. dr. ir. Wiendelt Steenbergen
on behalf of:
Biomedical Photonic Imaging
MIRA Institute
University of Twente
Source(s) of monetary or material Support: - Crowdfunding 'Pammografie'
- Stichting Achmea Gezondheidszorg
- Twente Graduate School

Intervention

Outcome measures

Primary outcome

The main study parameter is a set of photoacoustic breast images from healthy breasts, breasts containing malignant lesions and breasts containing benign lesions. Images from the subjects' breasts taken with conventional imaging modalities are collected (x-ray, ultrasound, MRI, pathology). The main objective is to investigate the feasibility of PAM 2 in breast cancer imaging, characterizing the photoacoustic appearances of different types of malignant and benign lesions. The photoacoustic images are described qualitatively.

Secondary outcome

All subjects are asked to fill out a questionnaire. The questionnaire contains questions on experience with measurement (comfort, burden) and personal questions about for example age, height and medical history.

Study description

Background summary

Breast cancer is the most common type of female cancer worldwide. Conventionally used imaging techniques (x-ray mammography, ultrasonography, MRI) have their limitations and drawbacks.

In this observational diagnostic clinical study with our second generation photoacoustic mammoscope (PAM 2), we want to investigate the feasibility of a new method, namely photoacoustics, in breast cancer imaging. The PAM 2 system performance is measured by comparing obtained photoacoustic images to conventional images and pathology results. The aim is to find photoacoustic image descriptors characteristic of malignant and benign breast lesions as well as of the healthy breast.

A maximum of 130 subjects (patients and healthy volunteers) are measured at the Medisch Spectrum Twente hospital in Oldenzaal (Netherlands) after being informed about the study and signing an informed consent form. The study population consists of adult women who come to the hospital with a lesion suspect for malignancy, which, after clinical investigation and diagnostic imaging is classified as BI-RADS 2, 3, 4 or 5. There is also a sub-population of adult healthy women. For each subject, the total measurement time is 8 minutes (two times four minutes), during which the subject lies prone on a bed with one of her breasts freely hanging in an imaging tank filled with warm water. For a subset of subjects, the pendant breast is supported by a holding cup.

Study objective

Breast cancer is the most common type of female cancer worldwide. Early detection has proven to have a positive influence on the prognosis and survival rate. An important aid in the detection and diagnosis of breast cancer is the use of medical imaging techniques. Conventionally used imaging techniques (x-ray mammography, ultrasonography, MRI) have their limitations and drawbacks. In the past years, a new method of imaging called photoacoustics (PA) has been developed and applied for breast cancer imaging at the University of Twente. PA combines high optical contrast with high ultrasound resolution. The contrast is based on light absorption by an increased amount of hemoglobin in and around malignancies. The method is non-invasive and harmless. The first generation Twente photoacoustic mammoscope (PAM 1) was tested in the clinic and was able to visualize known breast malignancies. We are now working with our (technically improved) second generation photoacoustic mammoscope (PAM 2), which has so far not been tested in a clinical setting. We want to investigate the feasibility of PAM 2 in breast cancer imaging. The PAM 2 system performance will be measured by comparing the obtained images of benign and malignant lesions to those of conventional imaging techniques and pathology results. Feasibility measurements will be performed with healthy volunteers.

Study design

The photoacoustic measurements are performed when a subject is already at the centre for mammacare (Medisch Spectrum Twente hospital in Oldenzaal, Netherlands) for conventional imaging / diagnosis. After informing her about the study and obtaining informed consent, the photoacoustic measurements are performed. When the measurements are completed, the subject is asked to fill out a questionnaire. Photoacoustic image reconstruction and analysis are conducted afterwards.

For healthy volunteer measurements:
As described, after a healthy adult woman decides to participate, an appointment is made to perform measurements at the Medisch Spectrum Twente hospital in Oldenzaal, Netherlands. When the measurements are
completed, the subject is asked to fill out a questionnaire. Photoacoustic image reconstruction and analysis are conducted afterwards.

Intervention

Measurement protocol:
When a patient comes to the centre for mammacare and meets the inclusion criteria, she is informed about and asked to participate in the study. When she decides to participate, both of her breasts are measured with the PAM 2 system after signing an informed consent form. The subject lies prone on a bed with one of her breasts through a round aperture. Under the bed, the imaging tank filled with warm water was installed, in which the breast hangs freely or is supported by a holding cup. The breast is illuminated by a laser and the hereby generated photoacoustic signals are detected by detectors also installed in the imaging tank. The tank rotates around the breast in order to obtain multiple projections. It takes approximately four minutes to image one breast with two excitation wavelengths. The contralateral (non-suspect) is also always imaged. The total measurement time will be equal to 8 minutes. However, the subject does not have to lie still for more than four minutes on

end. After the measurement, the subject is asked to fill out a questionnaire on her experiences with the measurement and her medical situation. No invasive procedures are performed during the photoacoustic measurement. Laser safety goggles are, under all circumstances, worn by all people present in the measurement room when the laser is operative. The laser fluence on the skin is kept below the maximum permissible exposure (MPE) for skin.

For healthy volunteer measurements:
A pamphlet with information on the clinical study will be used to recruit healthy volunteers. When a woman is interested to participate, she can contact the principal investigator to discuss the details. When she decides to participate in the study, meets the inclusion criteria and none of the exclusion criteria; an appointment will be made to perform the measurement. The measurement protocol of the photoacoustic measurements is similar to that for patients, described above.

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Eligibility criteria

Inclusion criteria

- Adult women who come to the mammapoli with a lesion suspicious for malignancy, which,

after clinical investigation and diagnostic imaging is classified as BIRADS 4 or 5, or BIRADS 2 or 3;
- Subjects who are fully competent to give informed consent.

For healthy volunteer measurements:
- Adult women;
- Subjects who are fully competent to give informed consent.

Exclusion criteria

- Subjects who have a cup size of D or larger OR subjects for whom the biggest size breast supporting cup is too small;
- Subjects who had a breast biopsy in the 6 months prior to this study;
- Subjects with bloody discharge, ulcers or wounds on the breast;
- Subjects with a history of surgery (including cosmetic surgery) or radiation therapy on the breast;
- Subjects who are currently undergoing chemotherapy.

For healthy volunteer measurements:
- Subjects who have a cup size of D or larger OR subjects for whom the biggest size breast supporting cup is too small;
- Subjects who have symptoms of breast cancer such as a palpable mass which might be attributed to breast cancer;
- Subjects who have had (a) benign breast lesion(s) in the past;
- Subjects who have had breast cancer in the past;
- Subjects who had a breast biopsy in the 6 months prior to this study;
- Subjects with blood discharge, ulcers or wounds on the breast;
- Subjects with a history of surgery (including cosmetic surgery) or radiation therapy on the breast;
- Subjects who are currently undergoing chemotherapy.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	05-12-2016
Enrollment:	130
Type:	Unknown

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion
Date: 08-06-2017
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 47204
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6010
NTR-old	NTR6508
CCMO	NL55871.044.15
OMON	NL-OMON47204

Study results

Summary results
n/a