Hybrid photoacoustic and ultrasound mammography

No registrations found.

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

Summary

ID

NL-OMON20835

Source
NTR

Brief title
PAMMOTH

Health condition

Breast cancer

Sponsors and support

Primary sponsor: University of Twente
Source(s) of monetary or material Support: EU Horizon2020

Intervention

Outcome measures

Primary outcome

The main deliverable is a set of PA/USCT breast images from healthy breasts, breasts containing malignant lesions, breasts containing benign lesions and all contralateral breasts. Furthermore, images acquired using conventional imaging modalities: x-ray and/or US and MRI will be collected in stage 2. For the patients who had to undergo a biopsy, we will also perform extensive pathology investigations as described in the study design.

Secondary outcome

We ask the radiologists to evaluate the breast density based on the MMG investigation. With this knowledge we can investigate the imaging performance and sensitivity of the PAMMOTH device in breasts with different densities.

All subjects will be asked to fill out a questionnaire. The questionnaire (F1) can be will contain questions on:
• Comfort / burden of the measurement;
• Personal information such as age, height, weight, breast size and moment in menstrual cycle at the time of measurement (if applicable).
This questionnaire gives us the opportunity to answer the following set of questions:
• Does the breast size influence the imaging performance and sensitivity of the PAMMOTH device?
• Does the menstrual cycle influence the imaging performance and sensitivity of the PAMMOTH device?
Other interesting questions may be defined during the study

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 third generation photoacoustic mammoscope (PAMMOTH), we want to test the feasibility of the PAMMOTH device in imaging breast cancer. Feasibility measurements will be performed with healthy volunteers. Using patient measurements, the performance of the PAMMOTH system will be measured, by comparing the obtained images of benign and malignant lesions to those of conventional imaging techniques 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 60 subjects (45 patients and 15 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 maximum total measurement time is 10 minutes (two times 5 minutes per breast), during which the subject lies prone on a bed with one of her breasts hanging in an imaging tank, supported by a cup, filled with warm water.

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 and second generation Twente photoacoustic mammoscope (PAM 1 and PAM2) were tested in the clinic. PAM1 was able to visualize known malginancies, while with the PAM2, significant improvements have been made in improving the image quality. We are now working on the even better, third version photoacoustic mammoscope (PAMMOTH). This is a hybrid system, combining PA with ultrasound computed tomography (USCT). The PAMMOTH device has so far not been tested in the clinical setting. With our clinical study, we want to test the feasibility of the PAMMOTH device in imaging breast cancer. Feasibility measurements will be performed with healthy volunteers. Using patient measurements, the performance of the PAMMOTH system will be measured, by comparing the obtained images of benign and malignant lesions to those of conventional imaging techniques and pathology results.

Study design

The photoacoustic measurements are performed when a patient 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.

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Eligibility criteria

Inclusion criteria

Healthy volunteers:
- Adult women;
- Subjects who are fully competent to give informed consent.

Extra criteria for patients:
- Adult women who present at the Centre for Mammacare with an anomaly in the breast, which, after clinical investigation and diagnostic imaging is suspect to be of an ICNST, ILC, DCIS, FA or cyst;
- Subjects who are fully competent to give informed consent.

Exclusion criteria

Healthy volunteers:
- Subjects with a (history of) breast disease;
- Subjects with a tattoo or irremovable piercings on/in the breast;
- Subjects who are pregnant or who are breastfeeding.
- Subjects with a known allergy for PVC
- Subjects who are not physically capable of climbing on the examination bed, who’s breast are too big to fit in the cup sizes or are not capable to lay still in prone position for the requested examination time.

Criteria for patients:
- Subjects who had a breast biopsy in the 6 months prior to this study;
- Subjects with bloody discharge, breast ulcers or -wounds;
- Subjects with a history of surgery (including cosmetic surgery) or radiation therapy on the breast;
- Subjects who are currently undergoing chemotherapy;
- Subjects with a tattoo or irremovable piercings on/in the breast;
- Subjects who are pregnant or who are breastfeeding;
- Subjects with contra-indication for breast MRI.
- Subjects with a known allergy for PVC
- Subjects who are not physically capable of climbing on the examination bed, who’s breast are too big to fit in the cup sizes or are not capable to lay still in prone position for the

requested examination time.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2020
Enrollment:	60
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	22-08-2019
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7992
Other	European Union's Horizon2020 Research and Innovation Action, H2020 ICT 2016-2017, Photonics 21 Public Private Partnership : Grant agreement No 732411 (PAMMOTH)

Study results