A new device (PAMMOTH) for hybrid photoacoustic and ultrasound mammoscopy to evaluate screening-detected abnormalities in the breast

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Primary: To investigate the performance of the PAM3(+) device in breast cancer imaging. With the performance we mean:1. The ability to visualize blood vessels and tumors in the mammary gland (PA)2. To extract oxygenation saturation estimations (QPAT…

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Breast neoplasms malignant and unspecified (incl nipple)
Study type	Observational non invasive

Summary

ID

NL-OMON54760

Source
ToetsingOnline

Brief title
Hybrid photoacoustic and ultrasound mammography

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
breast cancer, carcinoma of the breast

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Twente

Source(s) of monetary or material Support: eerste beurs: European Union's Horizon 2020 Research and Innovation Action;H2020 ICT 2016-2017;an initiative of the Photonics 21 Public Private Partnership;PAMMOTH grant agreement No 732411;tweede beurs: EU-REACT PAM3+ project

Intervention

Keyword: breast cancer, detection, photoacoustic imaging, ultrasound computed tomography

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 PAM3(+) 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

PAM3(+) device?

• Does the menstrual cycle influence the imaging performance and sensitivity of

the PAM3(+) 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. 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 in PA is based on light absorption by an increased amount of hemoglobin in and around malignancies. The method is non-invasive and is harmless. The first two generations Twente photoacoustic mammoscopes (PAM 1 & PAM 2) were tested in the clinic. PAM 1 was able to visualize known breast malignancies, and in PAM 2 the imaging quality was improved. We are now working with our (technically improved) third generation system (the PAM3(+) device), which is a hybrid system by combining PA with ultrasound computed tomography (USCT). We hope to visualize more anatomical information about the tumor by the combination of these modalities. The PAM3(+) device has so far not been tested in a clinical setting. In this study, we want to investigate the feasibility of the PAM3(+) device in breast cancer imaging. The PAM3(+) system performance will be measured by comparing the obtained images of benign and malignant lesions to those of conventional imaging techniques (x-ray mammography, ultrasonography, MRI) and pathology results. Next to that, feasibility measurements will be performed with healthy volunteers.

Study objective

Primary: To investigate the performance of the PAM3(+) device in breast cancer imaging. With the performance we mean:

1. The ability to visualize blood vessels and tumors in the mammary gland (PA)
2. To extract oxygenation saturation estimations (QPAT)
3. To visualize the breast morphology (USCT)

Secondary:
• To optimize the measurement protocol and general system performance;
Optimize patient positioning and breast stabilization
To develop an appropriate image reconstruction algorithm in
order to obtain an optimal contrast and resolution;
• To investigate the ability of the PAM3(+) device to assess lesion location
and size;
• To find out whether the PAM3(+) device is able to visualize the entire
mammary gland;
Investigating whether the blood present in the pectoralis
major muscle, positioned underneath the mammary gland can be visualized.
• To correlate PA/USCT breast images to clinical, pathological and conventional
imaging, in order to find PA image descriptors;
• To start with the development of a PA/USCT lexicon, as a lead for
radiologists to come to a diagnosis.
• To deduce additional criteria to be implemented in future clinical trials
with the PAM3(+) device;

Study design

This study is an observational feasibility study consisting of 2 stages. In the first stage the measurement procedure will be optimized using healthy subjects (maximum of 30 (2x15)). The second stage consists of a clinical feasibility study, performing the PAMMOTH measurements and in some cases MRI next to the normal workup in a maximum of 130 patients who present at the Centres for Mammacare with an anomaly in the breast.

Study burden and risks

Subjects in stage 2 will already be visiting this outpatient breast clinic. The PA and USCT investigations will be performed after the MMG and/or US investigations, but before the MRI and/or biopsy investigations. The patient will join the PAM3(+) study in the time the radiologists have to evaluate the acquired MMG and/or US images to decide upon the next steps. Patients who have to undergo a MRI investigation according to the normal work-up, which generally consists of BIRADS 3, 4 or 5 patients, will not experience any extra burden by participating in our study. However, patients from the MST who don*t have to undergo a MRI for their own standard diagnostic work-up (generally BIRADS 2), but do want to participate in our study will experience a slightly increased burden since they have to undergo an additional MRI investigation. This implies that we need an hour more of these patient*s time and that the patient has to travel to the MST in Enschede to undergo this extra MRI. Additional findings

rising from the MRI will, in case of BIRADS-3 or higher, bring additional diagnostics. This will only be applicable to a few patients. The patients will be informed about this.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

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. (only in Medisch Spectrum Twente)
- 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

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-11-2020
Enrollment:	160
Type:	Actual

Medical products/devices used

Generic name:	PAM3(+) device
Registration:	No

Ethics review

Approved WMO Date:	20-03-2020
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	17-06-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	17-10-2023
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
CCMO	NL71091.100.19
Other	NL7992