Visualizing breast lesions with the second generation Twente photoacoustic mammoscope (PAM 2)

Published: 01-11-2016
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Primary objective: To investigate the feasibility of PAM 2 in breast cancer imaging, characterizing the photoacoustic appearances of different types of malignant (stage 1A) and benign (stage 1B) lesions.Secondary objectives:- To test the measurement...

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

Summary

ID

NL-OMON47204

Source
ToetsingOnline

Brief title
photoacoustic mammography 2

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: Ministerie van OC&W,crowdfunding;Stichting Achmea Gezondheidszorg

Intervention

Keyword: breast cancer, detection, diagnosis, photoacoustic imaging

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. Photoacoustic images will be qualitatively described and compared to the outcomes of clinical investigation, conventional imaging and pathology. In stage 1A and 1B, we want to find photoacoustic markers indicative for malignant respectively benign lesions. The presence or absence of markers of malignancy will be evaluated in stage 1B. In both stages, photoacoustic appearance of healthy (contralateral) breasts will be investigated.

Secondary outcome

All subjects will be asked to fill out a questionnaire. The questionnaire 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).

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 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. Next to that, feasibility measurements will be performed with healthy volunteers.

Study objective

Primary objective:
To investigate the feasibility of PAM 2 in breast cancer imaging, characterizing the photoacoustic appearances of different types of malignant (stage 1A) and benign (stage 1B) lesions.

Secondary objectives:
- To test the measurement protocol and general system performance;
- To correlate photoacoustic breast images to clinical, pathological and conventional imaging in order to find photoacoustic image descriptors and investigate the ability of PAM 2 to assess lesion location and size;
- To find out whether PAM 2 is able to visualize the entire mammary gland;
- To develop an appropriate image reconstruction algorithm in order to obtain an optimal contrast and resolution;
- To deduce potential exclusion criteria to be implemented in future clinical studies with the PAM 2 (stage 2, will be submitted separately to the METC in future).

Study design

This study will be an observational, diagnostic study. The study will be divided into stage 0, stage 1A and stage 1B. The study will last one year and a maximum number of 130 subjects will be included, divided over stage 0, 1A and 1B.

Study burden and risks

In order to get a first indication of the performance of the system, we need to image healthy subjects, subjects with malignant lesions as well as subjects with benign lesions and contralateral healthy breasts. This makes the study

group-related to healthy volunteers and to patients who come to the mammapoli MST with either a BI-RADS 2 or 3 or a BI-RADS 4 or 5 lesion. The expected risk is negligible and the burden is minimal. There is no individual benefit for subjects participating in the study. The benefit is aimed at the future breast cancer population.

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

Stage 0:
- Adult women;
- Subjects who are fully competent to give informed consent.;Stage 1:
- Adult women who come to the mammapoli with a lesion suspicious for malignancy, which, after clinical investigation and diagnostic imaging is classified as BI-RADS 4 or 5 (stage 1A),

or BI-RADS 2 or 3 (stage 1B);
- Subjects who are fully competent to give informed consent.

Exclusion criteria

Stage 0:
- Subjects who have a cup size of D or larger;
- 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 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.;Deel 1:
- Subjects who have a cup size of D or larger;
- 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.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-12-2016
Enrollment:	130
Type:	Actual

Ethics review

Approved WMO Date:	01-11-2016
Application type:	First submission
Review commission:	METC Twente (Enschede)
Approved WMO Date:	24-11-2016
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	22-02-2018
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	21-06-2018
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	02-11-2018
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	09-01-2019
Application type:	Amendment
Review commission:	METC Twente (Enschede)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 20184
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL55871.044.15
OMON	NL-OMON20184