Visualization of breast cancer with the first generation photoacoustic mammoscope

Published: 02-11-2010
Last updated: 04-05-2024

1. To investigate the feasibility of photoacoustic breast cancer imaging as embodied in the first generation photoacoustic mammoscope; 2. To correlate the photoacoustic images to conventional diagnosis of the breast and therefore to find...

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

Summary

ID

NL-OMON39181

Source
ToetsingOnline

Brief title
photoacoustic 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: Ministerie van OC&W,Innovatie gerichte OnderzoeksProgramma's (IOP)-SenterNovem

Intervention

Keyword: Breast Cancer, Diagnosis, Imaging, Photoacoustics

Outcome measures

Primary outcome

Photoacoustic images will be compared with the outcomes of clinical investigation, conventional imaging, optical properties of healthy and malignant tissue and pathology. In the first stage of the study (3 months, 10 patients), the photoacoustic images will mainly be used to optimize the measurement and analysis methods. In the second stage of the study (18 months 50-70 patients), the images of the BIRADS 4 and 5 lesions will qualitatively be described in order to find photoacoustic markers that are indicative for malignancy and how they are related tot he optical properties of the patients breast tissue. In the third stage of the study (3 months, about 20 patients), which will only be reached if the results of the first two phases are promising, also non-cancerous breast (normal breast tissue and benign lesions - BIRADS 1,2)) will be investigated for the presence of the photoacoustic malignancy markers.

Secondary outcome

not applicable

Study description

Background summary

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 whole adult female population. Furthermore, of the conventional imaging techniques, X-ray mammography uses potential hazardous ionizing radiation and MRI requires injection of contrast agents. In the last years, researchers at 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 and provides, in theory, a higher sensitivity and specificity than X-ray mammography and ultrasonography. Photoacoustic imaging does neither require ionizing radiation nor contrast agents and does not exclude people with pacemakers. It is expected that the imaging is not influenced by the density of the breast and, therefore, that it can also be used in younger high-risk women. The clinical feasibility of photoacoustic mammography has been tested with realistic breast phantoms and in a small pilot study. We are now at the stage that a lot of clinical data is needed in order to guide the developments of this technique and to find photoacoustic parameters that are indicative for malignancy.

Study objective

1. To investigate the feasibility of photoacoustic breast cancer imaging as embodied in the first generation photoacoustic mammoscope;
2. To correlate the photoacoustic images to conventional diagnosis of the breast and therefore to find photoacoustic markers that are indicative for malignancy (phase 1 and 2);
3. To determine the optical characterization of and differentiation between benign and malignant breast tissue (phase II: DPS)
4. To effect technological changes based on clinical and patient*s experiences, and to use the results in the development of the second generation photoacoustic mammoscope (phase 1-3);
5. To find the appropriate image analysis methods in order to get the best contrast between cancerous and non-cancerous breast tissue within the patient (phase 1-3).

Study design

This study will be an observational and diagnostic study. The study will be divided into three stages. The total study will last for 2 years and a maximum number of 100 women will be included.

Study burden and risks

Because we want to investigate the clinical feasibility of photoacoustic imaging in symptomatic women, patients from the outpatient*s breast clinic are

needed. No risks are expected for the patients participating in the study and the burden is only minimal. There is no individual benefit for the patients participating in this study. The benefit of this study is concerning a large amount of the future breast cancer population.

Contacts

Public
Universiteit Twente

Dienstweg 1
Enschede 7522 NB
NL
Scientific
Universiteit Twente

Dienstweg 1
Enschede 7522 NB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Photoacoustic part:
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 3-5 (phase 1 and 2) or a BIRADS 1 or 2 (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.;DPS part:
1) all inclusion criteria for photoacoustic imaging;
2) patient who gave informed consent for the photoacoustic imaging study;
3) patient who will have a ultrasound-guided breast biopsy to investigate the lesion, which should be accessible with the VACORA biopsy system.

Exclusion criteria

Photoacoustic part:
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 or radiation therapy on the breast;
5) Patients who are currently undergoing chemotherapy.;DPS part
1) all under 'photoacoustic part'
2) patient who don't gave informed consent for the photoacoustic part
3) patient who use anticoagulantia;
4) patients from which the lesion is inaccessible with the VACORA biopsy needle.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2010
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	02-11-2010
Application type:	First submission
Review commission:	METC Twente (Enschede)
Approved WMO Date:	20-10-2011
Application type:	Amendment
Review commission:	METC Twente (Enschede)
Approved WMO Date:	29-01-2013
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

No registrations found.

In other registers

Register	ID
CCMO	NL30718.044.09
Other	TC=2945 (Nederlands Trial Register)

Study results

Date completed:	01-07-2013
Actual enrolment:	73