# Hybrid photoacoustic and ultrasound mammography

Gepubliceerd: 22-08-2019 Laatst bijgewerkt: 13-12-2022

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...

Ethische beoordeling Status	Positief advies Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

# Samenvatting

## ID

NL-OMON20835

Bron NTR

Verkorte titel PAMMOTH

#### Aandoening

Breast cancer

## Ondersteuning

**Primaire sponsor:** University of Twente **Overige ondersteuning:** EU Horizon2020

## **Onderzoeksproduct en/of interventie**

#### Uitkomstmaten

#### Primaire uitkomstmaten

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.

# **Toelichting onderzoek**

#### Achtergrond van het onderzoek

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 subpopulation 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.

#### Doel van het onderzoek

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.

#### Onderzoeksopzet

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.

# Contactpersonen

## **Publiek**

Universiteit Twente Maura Dantuma

+31534891043

## Wetenschappelijk

Universiteit Twente Maura Dantuma

+31534891043

# **Deelname eisen**

# Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

## Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

# Onderzoeksopzet

# Opzet

Туре:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

### Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-02-2020
Aantal proefpersonen:	60
Туре:	Verwachte startdatum

## Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

# **Ethische beoordeling**

Positief advies	
Datum:	22-08-2019
Soort:	Eerste indiening

# Registraties

# Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

# Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

# In overige registers

#### Register ID

NTR-new NL7992

European Union's Horizon2020 Research and Innovation Action, H2020 ICT Ander register 2016-2017, Photonics 21 Public Private Partnership : Grant agreement No 732411 (PAMMOTH)

# Resultaten