Diffuse Optical Tomography (DOT) and Magnetic Resonance Imaging (MRI) image fusion, development of methods in volunteers and validation in patients with benign cysts of the breast

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The purpose of this study is to develop and validate methods to fuse the molecular information of DOT-images with anatomical information of MRI-images of the human breast.

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

Summary

ID

NL-OMON36530

Source
ToetsingOnline

Brief title
fusion of MRI and DOT images

Condition

- Breast neoplasms benign (incl nipple)

Synonym
breast cysts, cysts of the breast

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: CTMM-MAMMOTH,CTMM-partners

Intervention

Keyword: benign cyst, fusion methods, MRI, optical mammography

Outcome measures

Primary outcome

Part A aims at adapting and fine-tuning the fusion methods developed with breast phantoms. In part B, the adapted methods will be validated using imaging data of 15 patients with benign cysts. Target Registration Errors (TRE, displacement vectors) will be calculated and should not exceed two voxels of the corresponding spatial resolution on the DOT images.

Secondary outcome

Secondary objectives include the training of personnel in handling patients on the PMS-DOT prototype in order to streamline current and upcoming studies (part A). Also, the features of two available optical matching fluids will be investigated.

Study description

Background summary

Imaging techniques play an important role in breast cancer management. The currently used modalities like X-ray mammography, Ultrasound and Magnetic Resonance Imaging have important limitations like low sensitivity, high costs, the use of ionizing radiation or compression of the breast.
Diffuse Optical Tomography (DOT) imaging provides three dimensional images of optical characteristics of the breast using near infrared light only and without breast compression. At the University Medical Center Utrecht, studies

using the Philips Medical Systems - Diffuse Optical Tomography (PMS-DOT) Prototype have been carried out in 2006-2007 with promising results. However, the prototype was not yet competing with standard diagnostic modalities.
Within the Centre for Translational Molecular Medicine (CTMM) - Mammary Carcinoma Molecular Imaging for Diagnosis and Therapeutics (MAMMOTH) project, breast cancer targeting probes are being developed, conjugated to fluorescent dye and made suitable for human optical imaging. This Fluorescence Molecular Imaging should greatly improve diagnostic performance and even holds the promise to outperform anatomical imaging modalities in the future. As fluorescence molecular imaging of the human breast is an uncharted area and previous clinical trials have indicated the anatomical information obtained from optical imaging is minimal, co-registration with an anatomical imaging modality such as Magnetic Resonance Imaging (MRI) will be necessary for further development. In this way, the interpretation of DOT-images will be ameliorated in upcoming fluorescence molecular imaging trials.

Study objective

The purpose of this study is to develop and validate methods to fuse the molecular information of DOT-images with anatomical information of MRI-images of the human breast.

Study design

This single center observational clinical study consists of a methods-development part (A) and a validation part (B).
In part A, healthy female volunteers will be imaged on the PMS-DOT system and MRI. Fusion methods will be adapted making use of the the collected data. In part B, patients diagnosed with ultrasound proven benign cysts will be imaged on both modalities to validate the methods developed in part A.

Study burden and risks

Optical imaging is a safe investigational procedure, the PMS-DOT system meets the Medical Device Directive requirements. The lasers are not harmfull, the optical matching fluid is biocompatible. No ionizing radiation is used and the breast is not compressed. Magnetic Resonance Imaging is a safe technique and commonly used in daily medical practice. No contrast agent is used.
The estimated risk classification for this study: minimal exceeding of negligible risk.

Contacts

Public

Universitair Medisch Centrum Utrecht

Heidelberglaan 100
3584 CX Utrecht
NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
3584 CX Utrecht
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Females age 18 years old or over , given written informed consent
Group A (volunteers): No known breast lesion
Group B (patients with benign cysts): Ultrasound proven benign cyst (BI-RADS 2)

Exclusion criteria

- Recent (surgical) interventions (including cytology, surgery) of the breast
- Piercings or tattoos on the breast
- Breast located skin disease
- Group B: cyst located close to the chest wall

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):	23-06-2011
Enrollment:	33
Type:	Actual

Medical products/devices used

Generic name:	Diffuse Optical Tomography System
Registration:	No

Ethics review

Approved WMO Date:	23-03-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	17-06-2011
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL33729.041.10