Clinical validation of the optical mammography system

Published: 18-07-2006
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The purpose of this study is to determine whether optical mammography performed on the PMS DOT has a potential in breast cancer diagnosis in patients with suspicious breast lesions.

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

Summary

ID

NL-OMON30324

Source
ToetsingOnline

Brief title
MONA LISA - 1

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
breast cancer, breast neoplasms

Research involving
Human

Sponsors and support

Primary sponsor: Philips
Source(s) of monetary or material Support: Contract met Philips Medical Systems

Intervention

Keyword: breast cancer, mammography, Optical tomography

Outcome measures

Primary outcome

Number and size of lesions and location within the breast will be recorded. The characteristics concerning contrast intensity and direction (i.e. higher or lower signal compared to background), and homogeneity will be scored for each lesion. The nature of the lesions (malignant/benign) will be determined by MR-mammography, and, if necessary, pathology report (reference standard).

The safety of the PMS DOT system will also be assessed.

Secondary outcome

not applicable

Study description

Background summary

Imaging techniques play an important role in breast cancer management. The currently used X-ray mammography has important limitations, such as its limited use in dense breast tissue and low sensitivity. Magnetic Resonance (MR) mammography is able to improve these issues only to some extent and is costly and time-consuming. Consequently, there is an urgent need for a low-cost, high-speed, accurate imaging tool of the breast. Optical mammography has great potential. A technologically advanced optical mammography system has recently been developed: the Philips Medical Systems Diffuse Optical Tomography system (from here onwards referred to as PMS DOT). It uses near infrared light at 4 different wavelengths to compose images of the optical properties of breast tissue. The relative concentrations of haemoglobin, lipid, and water can then be calculated. This could make discrimination between benign and malignant lesions possible, as has already been described in several clinical studies.

Study objective

The purpose of this study is to determine whether optical mammography performed on the PMS DOT has a potential in breast cancer diagnosis in patients with suspicious breast lesions.

Study design

This study consists of two parts. In Part A, 5 patients will be examined on PMS DOT to optimize the usage of the optical imager in order to streamline the study; In Part B, 25 patients will be asked to enter this study. The PMS DOT will be validated as part of the CE certification. This study is a first step towards using the PMS DOT in combination with a fluorescent contrast agent for the assessment of breast lesions.
The patients will be imaged on the PMS DOT system and they will undergo MR-mammography. Optical images will be obtained of both breasts. Evaluation contains the detection of lesions compared to MR-mammography.

Study burden and risks

The burden for participants is minimal: the optical investigations are non-invasive, not painful and not time-consuming (2 x 9 minutes). The safety risk related to the system expected is considered minimal, when entering this study. The system safety is not hampered, because: 1) Fluids, which come into contact with the skin, are biocompatible; 2) Lasers will satisfy the European Standard EN 60825-1 Safety of laser products Part 1; 3) A Hazard Analysis is held and follow up actions are executed. MRI is not harmful either, no ionizing radiation is used. The duration of MRI is 30 minutes at maximum.

Contacts

Public
Philips

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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

BIRADS 2-5 on X-ray mammography
Patients should have both breasts
Age > 18 years

Exclusion criteria

recent breast biopsy/fine needle aspiration

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):	20-07-2006
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	optical mammography
Registration:	No

Ethics review

Approved WMO Date:	18-07-2006
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	30-01-2007
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	NL11286.041.06