Measurement of the local optical properties of malignant and normal breast tissue

Published: 28-03-2011
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To measure the wavelength dependent differences in optical properties between normal and malignant breast tissue over a broad wavelength range (400-1000 nm).

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Miscellaneous and site unspecified neoplasms benign
Study type	Observational invasive

Summary

ID

NL-OMON36789

Source
ToetsingOnline

Brief title
optical properties of breast tissue

Condition

- Miscellaneous and site unspecified neoplasms benign
- Breast therapeutic procedures

Synonym
breast cancer, breast tumor

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: AgentschapNL

Intervention

Keyword: absorption coefficient, breast cancer, optical properties

Outcome measures

Primary outcome

The wavelength dependent difference in absorption coefficient between normal

and malignant breast tissue at different locations in the tumor.

Secondary outcome

N/A

Study description

Background summary

Photoacoustic mammography is currently under investigation as an alternative for X-ray mammography. Optimisation of the photoacoustic mammography image contrast involves determination of the optimal contrast wavelength.

Study objective

To measure the wavelength dependent differences in optical properties between normal and malignant breast tissue over a broad wavelength range (400-1000 nm).

Study design

Observational study.

Study burden and risks

The burden and risks associated with participation are minimal; optical measurements are performed with sterile optical needles with the patient under general anesthesia, prior to mastectomy. Measurements are only taken in tissue that will be removed by the surgeon. The total time taken by the measurements is less than 10 minutes. The patients will not benefit from the study.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr. Molewaterplein 50
3000 CA
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr. Molewaterplein 50
3000 CA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients undergoing modified radical mastectomy, with preferably palpable tumors at large distance from the musculus pectoralis.

Exclusion criteria

- Nipple sparing/skin sparing mastectomy
- Patients with silicone breast implants
- Patients with increased risk based on a poor general condition

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	09-02-2012
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	28-03-2011
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL34707.078.10