Value of breast thermal imaging

Published: 26-11-2010
Last updated: 04-05-2024

This study will evaluate the significance of TISENO for early detection of mamma carcinomas and benign breast diseases.

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

Summary

ID

NL-OMON34423

Source
ToetsingOnline

Brief title
Breast Thermal Imaging

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
breastcancer cysts

Research involving
Human

Sponsors and support

Primary sponsor: Sint Franciscus Gasthuis
Source(s) of monetary or material Support: Maatschap chirurgie SFG

Intervention

Keyword: breast, imaging, Thermal, TISENO

Outcome measures

Primary outcome

The goal of the study is evaluation of the TISENO technique in early detection

of breastcancer and its role in detecion of benign lesions.

Secondary outcome

none

Study description

Background summary

In the Netherlands 12000 women with breastcancer are diagnosed. The chance of having breastcancer lifetime is 12-13 %. Early detection is very important despite the improvement of diagnostic techniques and therapeutic options. Mammography and ultrasound are the conventional techniques in detection of breastcancer. This can be difficult in younger women with more dense glandular parenchyma. Therefore thermographic imaging can be useful in detecting breastcancer in some women.
TISENO (Thermal Imaging in SENOlogy) is a device for thermographic digitalized image reproduction using high-resolution liquid crystal plates for early detection of breast laesions. Angiogenesis, i.e. the formation of new blood vessels from a pre existent vascular system is a condition for tumors to grow and metastasize. The temperature will increase with the formation of the tumor and this can be thermal detected on the skin.

Study objective

This study will evaluate the significance of TISENO for early detection of mamma carcinomas and benign breast diseases.

Study design

In this prospective clinical study all new female patients will be included with an atypical mammography in population screening or with an abnormality on palpation or other complaints.
The patients will be examined physically and will be send for TISENO after a signed agreement (informed consent). The TISENO procedure will take about 5 minutes. Afterwards all patients will have a mammography and ultrasound or MRI.

These last techniques will be conclusive in the defintive diagnosis and therapy.

Study burden and risks

none.

Contacts

Public
Sint Franciscus Gasthuis

Kleiweg 500
3045PM Rotterdam
NL
Scientific
Sint Franciscus Gasthuis

Kleiweg 500
3045PM Rotterdam
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Women with a lesion of the breast (benign or malign)

Exclusion criteria

none

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2011
Enrollment:	500
Type:	Actual

Ethics review

Approved WMO

Date:	26-11-2010
Application type:	First submission
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (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	NL32619.101.10