

The diagnostic accuracy of Virtual Touch IQ in distinguishing benign from malignant lesions in breast

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With this study we will investigate whether it is possible to distinguish benign from malignant lesions with Virtual Touch IQ. This will decrease the need for additional biopsy. Furthermore it may decrease the false positive ratio of mammography...

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

Summary

ID

NL-OMON40711

Source

ToetsingOnline

Brief title

ELAN

Condition

- Breast neoplasms benign (incl nipple)

Synonym

breast lesions, breast tumor

Research involving

Human

Sponsors and support

Primary sponsor: Jeroen Bosch Ziekenhuis

Source(s) of monetary or material Support: niet van toepassing

Intervention

Keyword: benign, elastography, malignant, Virtual touch IQ

Outcome measures

Primary outcome

With this study we will investigate whether it is possible to distinguish benign from malignant lesions by measuring the shear wave velocity with Virtual Touch IQ.

Secondary outcome

Not applicable.

Study description

Background summary

Virtual Touch IQ elastography is a new ultrasound technique which provides measurements of tissue elasticity. It uses short duration acoustic pulses to produce localised displacements in tissue. These displacements can be monitored both spatially and temporally. This is called a shear wave. Shear wave velocity (SWV) is proportionnal to the elastic characteristics of the tissue being examined. Lesions in breast show changes in elasticity. To determine if a breast lesion is benign or malignant an additional biopsy is necessary. With this study we will investigate whether it is possible to differentiate benign from malignant lesions in breast with Virtual Touch IQ.

Study objective

With this study we will investigate whether it is possible to distinguish benign from malignant lesions with Virtual Touch IQ. This will decrease the need for additional biopsy. Furthermore it may decrease the false positive ratio of mammography and 2D ultrasound.

Study design

prospective cohort study

Study burden and risks

There are no risks involved. The examination will take about 15 minutes.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Patients with a lesion in the breast, detected by ultrasound,
age greater than 18 years
ability to give written informed consent

Exclusion criteria

Patient refusal
Typical simple cyst at ultrasound

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): 25-02-2015

Enrollment: 200

Type: Actual

Ethics review

Approved WMO

Date: 08-09-2014

Application type: First submission

Review commission: METC Brabant (Tilburg)

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	NL48114.028.14