The diagnostic accuracy of acoustic radiation force impulse elastography (ARFI) in distinguishing benign from malignant lesions in the breast.

Published: 25-04-2012
Last updated: 26-04-2024

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

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

Summary

ID

NL-OMON37752

Source
ToetsingOnline

Brief title
ARFI-breast

Condition

- Breast neoplasms malignant and unspecified (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: ARFI, benign, elastography, malignant

Outcome measures

Primary outcome

With this study we will investigate whether it is possible to dituinguish

benign from malignant lesions by measuring the shear wave velocity with ARFI.

Secondary outcome

not applicable

Study description

Background summary

Acoustic radiotion force impulse (ARFI) elastography is a new ulrasound technique which provides measurements of tissue elasticity. AFi 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 aditional biopsy is necessary. With this study we will investigate whether it is possible tot differentiate benign from malignant lesions in breast.

Study objective

With this study we will investigate whether it is possible to dituinguish benign from malignant lesions with ARFI. 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 a 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
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:	Recruitment stopped
Start date (anticipated):	01-07-2012
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	25-04-2012
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	NL39689.028.12