Radiowave radar imaging for breast cancer detection * a feasibility study

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Ethical review	Approved WMO
Status	Will not start
Health condition type	Breast neoplasms malignant and unspecified (incl nipple)
Study type	Observational non invasive

Summary

ID

NL-OMON44205

Source
ToetsingOnline

Brief title
MARIA * feasibility study

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
breast cancer, breast lesions

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Micrima Limited

Intervention

Keyword: breast cancer, radiowave radar imaging

Outcome measures

Primary outcome

Main endpoint of the study is the frequency of successful index lesion

detection, where successful is defined as *correlating to clinical findings

and/or histopathology determined by means of a needle biopsy*

Secondary outcome

-

Study description

Background summary

National breast cancer screening programs are overwhelmingly based on x-ray mammography which, in addition to concerns over cumulative exposure risk due to use of ionising radiation and discomfort / pain issues reported by patients, is also known to suffer from low sensitivity in patients who exhibit partly or exclusively dense breast tissue. In this study we will evaluate whether MARIA*, a new breast imaging modality based on GHz-band radio-frequency technology, can assist in the detection of lesions irrespective of breast density when applied to a symptomatic population.

Study objective

Our study aim is to assess whether MARIA* can provide diagnostic information that can supplement, and in some cases, replace mammography as a tool in the symptomatic workflow. We will also seek patient feedback on this non-ionising, non-compressing, whole-breast method of imaging,

Study design

This is a single-centre Post-Approval device study in 200 women who attend a symptomatic clinic

Study burden and risks

Our approach allows to test the feasibility of this highly innovating approach to breast cancer detection, with minimal negative effects or possible complications. With respect to gains in quality of life in terms of ease and speed of treatment, body image and recovery from treatment.
While there is no direct benefit nor detrimental effect from this study to the patients participating, the study may have large implications for many women, as breast cancer remains the most common cancer in women, and all currently available techniques have clear limitations that might be overcome by MARIA.

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

* Female sex.
* 19 years or older.
* Symptomatic breast lesion
* Able to provide informed consent.

Exclusion criteria

* Male sex.
* 18 years or younger.
* Unable to provide informed consent.
* Unable to lie in the prone position
* Patients who have undergone biopsy less than 5 days before the MARIA* scan
* Patients with implanted electronics.
* Patients with nipple piercings (unless they are removed prior to the MARIA* scan)
* Breast sizes smaller than AA or greater than 1L in volume

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	200
Type:	Anticipated

Medical products/devices used

Generic name:	MARIA
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	23-01-2018
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL62107.091.17