Comparison of low-dose spiral breast CT with MRI in major indications of MRI for breast diagnostics

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The purpose of the study is to provide comparative analysis of breast imaging modalities of BCT (nu:view) compared to MRI.

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

Summary

ID

NL-OMON56808

Source
ToetsingOnline

Brief title
ldBCT-MRI-C

Condition

- Breast neoplasms malignant and unspecified (incl nipple)
- Breast disorders

Synonym
Breast cancer, diagnostic imaging of the breast

Research involving
Human

Sponsors and support

Primary sponsor: AB-CT-Advanced Breast-CT GmbH
Source(s) of monetary or material Support: Industry

Intervention

Keyword: Breast cancer, Breast Imaging, Computer Tomographie, Magnetic Resonance Imaging

Outcome measures

Primary outcome

The primary objective is to demonstrate non-inferiority of CE-BCT with CE-MRI

in the BI-RADS detection at the lesion level in the diagnosis of

(i) inconclusive findings in conventional imaging or

(ii) preoperative staging or

(iii) evaluation of therapy response in the neoadjuvant chemotherapy setting or

(iv) occult primary breast carcinoma or

(v) prosthesis imaging or

(vi) screening of women with familial increased risk for the development of

breast cancer or

(vii) finding the cause of hemorrhagic nipple discharge or

(viii) axillary lymph node metastasis suspected to originate from breast

tissue.

Secondary outcome

The secondary objective is to collect data for comfort of CE-BCT and CE-MRI

using a patient questionnaire of closed questions.

Study description

Background summary

The diagnostic quality of MRI of the breast has made this method a gold

standard in the imaging of senologic lesions. Low-dose dedicated breast CT (BCT) with single photon-detection (nu:view, developed by AB-CT - Advanced Breast-CT GmbH) has emerged as a fully 3D imaging modality that uses ionizing radiation comparable to 2D mammography and has its intended use in helping with diagnosis in diagnostic breast imaging.
The investigation is designed as a prospective non-randomized intra-individual cohort procedure comparison between the imaging platforms, nu:view and MRI. Across 3 hospital-based study sites in two countries, study participants (patients who meet study criteria and have consented) sequentially receive nu:view imaging and, with a delay of up to one week (preferably on the same day), MRI imaging. At both times, patients receive contrast agent. Images generated from breasts are evaluated by three independent radiologists and their scores and interpretations are statistically evaluated. The research aim is to demonstrate non-inferiority of BCT compared with MRI in major indications of MRI for breast diagnostics.
The perceived gain in the study is to generate data on clinical performance of the BCT device nu:view and on the procedure that could be supportive of a tailored use of nu:view in patients with major indications of MRI for breast diagnostics.

Study objective

The purpose of the study is to provide comparative analysis of breast imaging modalities of BCT (nu:view) compared to MRI.

Study design

Prospective non-randomized intra-individual multicenter, multinational cohort comparison of the diagnostic quality of contrast enhanced (CE) breast CT to CE MRI in major indications of MRI for breast diagnostics.

Study burden and risks

The following adverse events (risks) have been described with the injection of contrast-enhancing agents for CT and MRI examinations:

- Allergic reactions up to and including anaphylactic shock.
The contrast agent that is to be administered to you is a common X-ray contrast agent that is used millions of times every day all over the world. The administration of this contrast medium carries certain risks of side effects.
In principle, an allergic reaction to the contrast medium is possible. Patients with a known allergy to X-ray contrast media (this must be distinguished from allergies to MR contrast media!) cannot be included in the study.

However, allergic symptoms can also develop for the first time in people with no known allergy. These can correspond to harmless symptoms that do not require

treatment, such as palpitations or a skin rash. These occur in about 2.5% of cases. Extremely rarely (in approx. 0.0003% of cases), complications requiring treatment such as shortness of breath or cardiovascular arrest can occur. In such cases, expert emergency care is of course provided.

- Kidney damage with contrast medium-induced nephropathy (non-inflammatory disease of the kidneys)
In principle, the contrast medium can damage kidney function. However, this is only to be feared if the kidney function is already damaged. You will therefore be checked for kidney function by a laboratory test before the examination as part of the clinical routine.

- Hyperthyroidism (hyperthyroidism) to thyrotoxicosis (acute exacerbation of hyperthyroidism) in patients with existing hyperthyroidism.
As the contrast medium contains iodine, your thyroid function will be checked in advance by a laboratory test as part of the routine clinical procedure.

- Extra-venous injection with infection, i.e. the vein was not hit properly during the injection and the contrast medium was injected into the tissue, which can then become inflamed.
The contrast medium is given via a previously inserted venous indwelling cannula on the arm (venous access, "brown cannula"). Accidental leakage of the contrast medium from the vessel (extravasation) is conceivable, but can be largely avoided by good placement and testing with saline solution by the doctor.

CT (computer tomography) is always associated with a low radiation exposure. The radiation exposure is about half the dose you receive annually from natural radiation sources.

- The level of risk (in terms of the approximate additional risk of cancer to an adult from the scan) to the breast from CT scanning at an effective dose of about 0.5-0.9 mSv as used in this study can be considered "very low risk" (1 in 100,000-1 in 10,000).

The MRI machine works with a strong magnetic field, which is why wearers of a pacemaker, for example, may be excluded from this examination method. Possible risks can also be:

- Feeling warm, cold or tingly
- headache
- General feeling of discomfort
- Skin irritation
- In some cases, MRI contrast media also cause allergic reactions.

However, some people do not tolerate the contrast medium so well. These are mainly patients with kidney dysfunction. They excrete the contrast medium only

poorly. Therefore, the doctor always checks the patient's kidney function before administering the contrast medium.

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

1. Sex: female
2. Age: at least 18 years
3. Inconclusive findings in conventional imaging or preoperative staging or evaluation of therapy response in the neoadjuvant chemotherapy setting or imaging of the breast after breast-conserving therapy or prosthesis imaging or screening of women with hereditary or finding the cause of hemorrhagic nipple discharge or familial increased risk for the development of breast cancer or axillary lymph node metastasis suspected to originate from breast tissue

4. Persons able and willing to understand and sign informed consent form

Exclusion criteria

1. Known pregnancy or breastfeeding
2. Presence of BRCA1 or BRCA2 allele
3. Insufficient renal function (MDRD)
4. Dysfunction of the thyroid gland (TSH degradation)
5. Known allergy or intolerance against iodine-containing contrast enhancing agents or MRI contrast enhancing agents
6. Patients with paramagnetic or magnetic material inside the breast, claustrophobia and other exclusion criteria for MRI

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-08-2023
Enrollment:	300
Type:	Anticipated

Medical products/devices used

Generic name:	nu:view
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	03-11-2023
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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
ClinicalTrials.gov	NCT05989022
CCMO	NL84097.058.23