Rapid Access to Contrast-Enhanced spectral mammogRaphy (RACER): a more efficient work-up of women recalled from breast cancer screening

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

Summary

ID

NL-OMON52927

Source
ToetsingOnline

Brief title
RACER

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
breast cancer, breast neoplasma

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht

Source(s) of monetary or material Support: Ministerie van OC&W,ZonMW,GE Healthcare,GE Healthcare (cofinanciering)

Intervention

Keyword: Breast cancer, Contrast-enhanced spectral mammography, Screening

Outcome measures

Primary outcome

Primary study parameters are the diagnostic performance of CESM as compared to conventional mammography, defined as sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV), area under the ROC curve (AUC).

Secondary outcome

Secondary study outcomes are days to final diagnosis for both study arms, patient experienced anxiety (as measured by State-Trait Anxiety Inventory (STAI) and EQ5D questionnaires) for both approaches, and a cost-effectiveness and budget impact analysis.

Study description

Background summary

Approximately 70% of all recalls from our breast cancer screening program are *false-positives* (FPs). These FPs generate (unnecessary) patient anxiety and health care costs. For this population, a new breast imaging tool, contrast-enhanced spectral mammography (CESM) showed to be an excellent problem-solving tool. In CESM, a dual-energy mammography is performed after administration of iodine-based contrast. After image acquisition, a radiologist will read two different images per breast and per projection view: one low-energy image (which is similar to a regular mammogram) and one recombined image, which shows areas of contrast enhancement. The added information of contrast capturing lesions increases the diagnostic performance compared to conventional mammography, increasing both cancer detection (sensitivity) and

reducing false-positive findings (increased specificity).
In current standard care, women recalled from screening for a suspicious breast lesion first visit their general practitioner (GP) and then a hospital*s breast nurse/surgeon before visiting a radiologist. Hence, many recalled women visit various physicians unnecessarily, since disease prevalence in this population is only 30%. Since sensitivity of full-field digital mammography (FFDM) decreases in dense breasts and general specificity of FFDM is limited, many women are undergoing follow-up even when the initial work-up did not detect any malignancies. Consequently, a rapid access to a more accurate breast imaging modality (i.e. CESM) should in theory be more accurate, more patient friendly and cost-efficient.

Study objective

The RACER project studies a more efficient approach based on (rapid access to) CESM, primarily resulting in less follow-up exams due to the superior specificity of CESM over FFDM. In addition, otherwise occult cancers will be detected in the women undergoing CESM, since it*s sensitivity is slightly higher. In this study, women are directly recalled for CESM. If this exam is negative, women are immediately reassured by the radiologist. Only if an abnormality remains suspicious on CESM women will undergo further tissue sampling and referral to a breast cancer clinic. Consequently, rapid access to CESM is more accurate, will lead to less unnecessary imaging, interventions or follow-up, is more patient-friendly and is less expensive than current usual care.

Study design

Multicenter, randomized controlled clinical trial.

Intervention

For the intervention group, rapid access to CESM is guaranteed. Prior to the exam, a questionnaire will be used to screen for risk factors for using iodine-based contrast agents (this is common practice in many Radiology departments). In a typical CESM exam, a intravenous catheter is placed in antecubital vein and two minutes prior to image acquisition the contrast agent is administered (Ultravist 300 or Xenetix 300, 1.5 mL/kg body weight, flow rate 3 mL/s, followed by saline flush). Then, mammography images are acquired of both breasts in two standard projection views, with additional views being requested by the radiologist on call when deemed necessary (the imaging protocol is similar to common clinical practice). The image acquisition with the breast compressed in mammography paddles can sometimes be painful, but the additional time for the acquisition of a CESM image is only max. 4 seconds for a single exposure. After completion of the exam, the intravenous catheter is removed.

The most common diagnoses in recalled women are: (1) cysts, (2)superimposition of glandular tissue mimicking breast cancer, (3) benign lesions, or (4) breast cancer or ductal carcinoma in situ. Final diagnosis or outcome is acquired as follows (per diagnostic category and with bypassing visits to breast clinic in most cases): (1) CESM showing a so-called *eclipse sign*, pathognomonic for cysts; (2) a negative CESM exam with no suspect lesion on both low-energy and recombined image; (3) CESM exam, including targeted ultrasound, and core biopsy or fine needle cytology aspiration for pathological diagnosis; (4) like group 3. Since many false-positive recalls are caused either by cysts or by superimposition densities, CESM prevents many unnecessary additional exams or biopsies. In scenario*s 1 and 2, a minimum of one doctor visit (breast clinic) would become unnecessary, whilst the omission of follow-up strategies such as breast MRI or follow-up visits after 6 or 12 months will result in saving another 1 to 2 doctor visits in scenario 2. The most important strength of the investigated intervention is the reduction of false positive findings and the number of unnecessary doctor visits. A second advantage of offering rapid access to CESM in recalled women is the slightly higher accuracy of CESM for detecting breast cancer.

Study burden and risks

During the CESM exam patients will undergo a venous puncture for the i.v. catheter. The administration of contrast can sometimes results in warm sensations, a strange taste in the mouth or nausea. These complaint usually resolve spontaneously within 30 seconds. Undergoing a mammographic exam can be painful for some women, but the additional compression time for CESM is max. 4 seconds longer, making the discomfort of the compression comparable to standard mammography.
Patients allocated to the experimental (CESM) study arm will receive a slightly increased radiation dose (ca. 2.8 mGy versus normally 1.6 mGy per exposure).
The use of iodine-based contrast agents could result in a hypersensitivity reaction or in severe cases even anaphylatic shock. I taan also cause a often self-limiting decreased renal function. However, the risks of these CESM disadvantages are very limited (<1%).

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

Included are women able to provide informed consent and recalled from breast cancer screening for a suspicious breast lesion during the 18-month study inclusion period.

Exclusion criteria

Exclusion criteria are contra-indications for the use of iodine-based contrast agents (allergies), severe renal insufficiency or risk for contrast-induced nephropathy.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Health services research

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-04-2018
Enrollment:	528
Type:	Actual

Ethics review

Approved WMO Date:	18-01-2018
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	07-11-2018
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	26-06-2019
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	05-06-2020
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	07-08-2020
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit

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	NL62788.068.17