Reduced contrast administration in contrast-enhanced spectral mammography (CESM)

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CESM is a novel mammography technique that has been shown to be superior to conventional full-field digital mammography (FFDM). In a CESM exam, iodine based contrast agents, similar to those used in for example computed tomography (CT) exams, are...

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

Summary

ID

NL-OMON45266

Source
ToetsingOnline

Brief title
Reduced contrast administration in CESM

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
breast cancer

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: breast cancer, contrast administration, Contrast enhanced spectral mammografie

Outcome measures

Primary outcome

All exams will be reviewed by two expert CESM radiologists, blinded for

contrast dose used, final tumor pathology and extent, and each other*s results.

The primary study parameter will be assessed for both the clinical and reduced

CESM exam and will consist of maximum tumor diameter. Final tumor pathology

results as assessed on the surgical specimen will serve as the gold standard.

Secondary outcome

Enhancement measurements for breast cancer detected with the clinical CESM exam

(reference) compared to the (experimental) CESM exams with varying (lower) dose

concentrations.

Study description

Background summary

The optimal dose of iodine based contrast agents used in contrast-enhanced spectral mammography (CESM) is unknown. If CESM, performed with lower dose of iodine based contrast agent, visualizes a tumor comparable to CESM with regular dose of contrast agent, patients can receive less contrast agent for CESM in future and thereby risking less side effects of the contrast agent.

Study objective

CESM is a novel mammography technique that has been shown to be superior to conventional full-field digital mammography (FFDM). In a CESM exam, iodine based contrast agents, similar to those used in for example computed tomography (CT) exams, are used. However, there is currently insufficient knowledge on the optimal dose of iodine based contrast agents used in CESM.

Study design

Cross-sectional diagnostic study.

Intervention

The diagnosis of breast cancers was made by using a well-validated protocol of our institute using an intravenous administration of iopromide (Ultravist 300, 1.5 mL/kg bodyweight). In order to study whether CESM remains unchanged at smaller amounts of contrast administration, a second CESM exam will be performed within one week of the first with a an alternative amount of contrast, it being either 80%, 60% or 40% of the original contrast dose. The settings of the CESM unit will remain unchanged.

Study burden and risks

A CESM exam has several disadvantages or potential complications. However, they are very limited and consist of an intravenous catheter placement and contrast administration, risk of analphylactic shock and renal failure due to the contrast administration and an increased radiation dose due to a second (CESM) exam. The risks of these potential complications are limited: intravenous catheter placement and contrast administration are extensively used in clinical practice and rare result in relevant complications, especially since only patients with adequate renal clearance are included; the risk of an anaphylactic adverse event is neglible since all patients have already received a clinical CESM exam prior before the second exam.

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. Female patient with histopathogically confirmed invasive breast cancer who recently underwent a clinical CESM exam without complications;
2. Treated with primary surgery;
3. Willing and able to undergo all study procedures;
4. Has personally provided written informed consent.
5. Age * 18

Exclusion criteria

1. Pregnancy
2. Allergy for any of the ingredients of (Ultravist) contrast agent
3. Being unable to give informed consent in person
4. History of coronary arterial disease or unstable angina
5. Acute or chronic severe renal insufficiency (glomerular filtration rate < 45 mL/min/1.732)

Study design

Design

Study phase:	4
Study type:	Interventional
Masking:	Double blinded (masking used)
Control:	Uncontrolled

Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-06-2017
Enrollment:	63
Type:	Actual

Ethics review

Approved WMO

Date:	01-03-2017
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NCT03008031
CCMO	NL59189.068.16

Study results

Date completed:	30-04-2020
Actual enrolment:	11

Summary results
Trial ended prematurely