Assessing the optimal amount of tissue sampling in contrast-enhanced biopsy

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To determine the minimum number of CESB-guided tissue samples needed to establish a final histopathological biopsy diagnosis for ROLs.

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

Summary

ID

NL-OMON55929

Source
ToetsingOnline

Brief title
CESB

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
Breast cancer, breast tumor

Research involving
Human

Sponsors and support

Primary sponsor: Zuyderland Medisch Centrum
Source(s) of monetary or material Support: Hologic

Intervention

Keyword: biopsy, breast neoplasm, mammography

Outcome measures

Primary outcome

The primary study aim will be to calculate the cumulative diagnostic yield per specimen, enabling us to define a minimum number of biopsies required (or tissue volume needed) to establish a reliable diagnosis using CESB.

Secondary outcome

Secondary study outcomes will be general parameters of the biopsy procedure itself, such as patient characteristics, histopathological results, pain experienced during the procedure, and complication rates (hematoma, infection).

Study description

Background summary

Contrast-enhanced mammography (CEM) is an emerging breast imaging modality that is based on dual-energy mammography and the injection of iodinated contrast agent. Studies have shown that the diagnostic accuracy of CEM is consistently superior to full-field digital mammography (FFDM), even matching the accuracy of breast MRI. A typical CEM study consists of a low-energy image (equal to a FFDM image) and a recombined image (in which areas of contrast enhancement can be appreciated). However, the situation can occur that lesions are visible only on the recombined (contrast) images (in this protocol defined as *recombined-only lesions* or ROLs). In these cases, we cannot fall back on conventional stereotactic biopsy since there is no correlate on low-energy (mammographic) images, nor is there a correlate on targeted ultrasound. In these cases, women need to *contrast-enhanced stereotactic biopsy* (CESB) to achieve a final tissue diagnosis.
However, experiences with CESB are still limited and one of the most urgent questions that need to be answered is the amount of tissue sampling that is required to reach a final diagnosis. With conventional stereotactic biopsy, often for calcifications, the presence of calcifications can be confirmed with specimen radiography. However, with ROLs there is no visual confirmation possible to confirm the accurate positioning of the biopsy. Hence, we need to study where the cut off will be in terms of tissue sampling volume needed (i.e., number of biopsies) for a reliable diagnosis.

Study objective

To determine the minimum number of CESB-guided tissue samples needed to establish a final histopathological biopsy diagnosis for ROLs.

Study design

Prospective, single center, observational cohort study.

Study burden and risks

The burden and risk for participating subjects is not increased in this study. Participants recently underwent CEM, thereby proving that they have no relevant renal insufficiencies to receive a second dose of contrast agent and proving that they have no hypersensitivity reactions to the contrast agent itself. The biopsy procedure itself is comparable with that of a standard stereotactic biopsy (the only difference is the administration of contrast via an intravenous catheter) and is associated with a very small risk of hematoma or infections. However, participation in this study do not increase these risks.

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 women are older than 18 years of age, with a recent finding on CEM requiring CESB (a so-called 'recombined image only lesion' or ROL). Only women able to provide written informed consent will be considered for this study.

Exclusion criteria

Excluded are all men (male sex), and women (female sex) who are contra-indicated for CESB (for example, with impaired renal function or known hypersensitivity reactions to iodinated contrast). Also excluded are pregnant women.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-10-2023
Enrollment:	150
Type:	Actual

Medical products/devices used

Generic name:	Contrast Biopsy
Registration:	No

Ethics review

Approved WMO Date:	05-09-2023
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	25-04-2024
Application type:	Amendment
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

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	NL84611.096.23