Combining contrast enhanced mammography and radio-active free magnetic seed localization of non-palpable breast tumors: A feasibility study

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To test whether the use of magnetic localization seeds causes image artifacts on CEM.

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

Summary

ID

NL-OMON56142

Source
ToetsingOnline

Brief title
CEMMAG

Condition

- Breast neoplasms malignant and unspecified (incl nipple)
- Breast therapeutic procedures

Synonym
breast cancer, breast tumor

Research involving
Human

Sponsors and support

Primary sponsor: Zuyderland Medisch Centrum
Source(s) of monetary or material Support: Sirius Medical (in kind)

Intervention

Keyword: Breast neoplasms, Localisation, Mammography

Outcome measures

Primary outcome

The primary study aim will be to test whether the magnetic seeds caused any disturbing artifacts on CEM images. For this purpose, two blinded radiologists will score the images for the presence of any artifacts and if present, if these are to such an extent that they would hamper diagnostic evaluation of the images.

Secondary outcome

As secondary study, we will document technical success rate of seed deployment and retrieval during surgery, including the assessment of the surgical margins (positive or negative).

Study description

Background summary

Breast cancer patients are increasingly treated with neoadjuvant chemotherapy for various reasons. These women receive chemotherapy before any surgery is performed. Many of these tumors need preoperative seed localization to help guide the surgeons to the site of the tumor within the breast. In many hospitals, a radioactive I-125 seed is used for this purpose, which has several disadvantages, such as a slight increase in radiation dose and extensive administrative regulations to monitor the location of the seed at any time (required by law). This administrative work is time consuming, elaborate and prone to errors. Therefore, interest is shifting towards to use of

non-radioactive seeds, such as the magnetic seeds used in this study. A drawback of these seeds is the fact that they cause large susceptibility artifacts on (magnetic!) MRI of the breast. Breast MRI is the most accurate modality to monitor response to therapy of these women. CEM, an emerging breast imaging technique, has shown to achieve comparable results with regard to response monitoring but uses no magnetic fields. Hence, CEM might be an attractive alternate response monitoring tool in patients treated with neoadjuvant chemotherapy and having a magnetic seed a surgical marker. To this point, however, no study in humans has confirmed that this is indeed the case.

Study objective

To test whether the use of magnetic localization seeds causes image artifacts on CEM.

Study design

Observational feasibility study.

Study burden and risks

The burden and risk for participating subjects are very small. In regular care, a radioactive I-125 seed is placed in the breasts of these women, checking the position with (conventional) FFDM. For this purpose, the iodine seed is replaced with a (radioactive-free) magnetic seed (Sirius Pintuition). The latter did not show any relevant imaging artifacts prior to this study in imaging phantoms (i.e., chicken breasts containing magnetic seeds). Therefore, we feel confident that these seeds will not show artifacts on clinical CEM image, but this needs to be confirmed before additional studies regarding the clinical application of CEM and magnetic seeds combined can be safely performed. The only additional disadvantage for participants is the slight increased radiation dose of the (extra) high-energy image CEM image, which is an increased radiation dose to the breasts of 50-80%. However, these women are all diagnosed with breast cancer requiring adjuvant radiotherapy, which uses radiation doses much, much higher than a single mammographic exposure.

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

Women scheduled for breast conservative therapy for a non-palpable breast lesion requiring image-guided localization using a magnetic seed.

Exclusion criteria

Unable to provide written informed consent. Age <18 years. Pregnancy.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-09-2023
Enrollment:	20
Type:	Actual

Medical products/devices used

Generic name:	Pintuition
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	08-03-2023
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)
Approved WMO Date:	30-10-2023
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	NL83090.096.22