Pilot for high-resolution SPECT imaging of breast cancer lumpectomy specimens for 3D identification and quantification of resection margins.

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Pilot for determining the feasibility and image quality of high resolution Tc99m-SestaMIBI imaging of lumpectomy specimens for detection, localization, and quantification of resection margins.

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

Summary

ID

NL-OMON41922

Source
ToetsingOnline

Brief title
High-resolution SPECT of breast cancer lumpectomy speciments

Condition

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

Synonym
Breast cancer, Breast carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Nederlands Kanker Instituut
Source(s) of monetary or material Support: Afdeling Nucleaire Geneeskunde;NKI-AVL

Intervention

Keyword: Breast cancer, High-resolution SPECT, Resection margins

Outcome measures

Primary outcome

Main study parameter/endpoint

The main study endpoint is de correlation between pathology and the images obtained by the U-SPECT+/CT. This correlation allows quantification of the accuracy of tumour imaging in breast cancer specimens using SestaMIBI. The outcome will be accuracy in mm and a visually determined correlation of pathology images with the SPECT/CT images.

Secondary outcome

Secondary study parameters/endpoints

• Endpoint: By using the list mode of the U=SPECT and reconstruct images at different acquisition times a minimal injected dose can be determined. By the same list mode the optimal scan-time can also be evaluated. Acquisition, reconstruction, and filtering options can be compared to determine the optimal settings.

o The outcome will be a minimal dose in MBq, a minimal scan-time, and the advices scan and reconstruction parameters.

• Endpoint: The U-SPECT+/CT will image the SestaMIBI distribution within the specimen and the I-125 seed is visible too. A comparison between the SestaMIBI in the specimen, the I-125 seed, and the resection margins can be made.

o Outcome values are the distance of the I-125-seed to the tumour border in mm, the distance between the centre of the tumour according to the SestaMIBI distribution and the location of the I-125-seed in mm.

Study description

Background summary

A small breast tumor can be treated safely with breast-conserving surgery. This leads to a very high chance of local control of the disease, as long as the resection is radical microscopically and the remaining breast tissue is adequately irradiated.

The treatment after lumpectomy is largely dependent on the evaluation of the resection margins. If the tumor reaches into the resection margin microscopically, a re-excision is indicated. When the tumor is too close to or in the resection margin, this determines the location of an extra 'boost' during radiation treatment.

Although the margins of a specimen are marked with sutures and/or ink, the evaluation of resection margins in a lumpectomy specimen is challenging due to distortion of the specimen. It is also impossible for the pathologist to examine the entire specimen microscopically; only a selection of slices can be viewed based on visual inspection of the sample. Therefore it is possible that a close- or positive resection margin is missed in some cases, is not located correctly, or not measured correctly. This might lead to suboptimal treatment with surgery or radiotherapy and thereby raising the chance for a local relapse of disease.

The radioactive tracer Technetium-99m-SestaMIBI is accumulated in breast tumors. Single photon emission computed tomography (SPECT) for imaging of this tracer, and sometimes in combination with CT for anatomical localization, is a known technique for detection of breast cancer. However, due to a limited resolution, this technique is only suitable for imaging of macroscopic tumors.

At the AVL a high-resolution SPECT/CT scanner is available. Although this is a

pre-clinical scanner, is can also be used for scanning of tissue specimens with maximum dimensions of about 4x4x8 cm. With this equipment, molecular imaging with high sensitivity can reach a spatial resolution of approximately 0,25 mm. The current clinical imaging equipment does not reach these specifications.

The hypothesis is that with these high-resolution SPECT images, the pathologist can be made aware of regions with a high risk for close or irradical resection margins prior to histopathological examination. Also the location of a positive resection margin can be identified more easily using the images. To determine the value of this new methodology, the image quality and feasibility of high-resolution SPECT/CT of lumpectomy specimens must be evaluated.

Study objective

Pilot for determining the feasibility and image quality of high resolution Tc99m-SestaMIBI imaging of lumpectomy specimens for detection, localization, and quantification of resection margins.

Study design

Five days prior to surgery the patient scheduled for lumpectomy with proven cT1 cNx invasive ductal carcinoma (IDC) (n=3), ductal carcinoma is situ (DCIS) (n=3) receives all patient information on paper and orally from one of the involved researchers. The patient consents for a SestaMIBI-99m injection at the day of surgery, preoperative imaging at the nuclear medicine department, and the patient*s tumour specimen is scanned by high-resolution SPECT after surgery prior to standard pathological evaluation.

During surgery 500MBq Technetium-99m (Tc-99m) SestaMIBI is intravenously administered in the contralateral arm by a nuclear physician or one of the researchers with a radiation expertise level III certificate.

For the surgeon and patient the whole surgical procedure is according to standard clinical protocol, however the time between injection and excision should be minimally 10 minutes. Straight after the excision of the specimen, the specimen is placed in a Perspex container and transported in an iced box to the U-SPECT+/CT. The anatomical orientation is marked at the specimen for correlation of the images.
A 3D SPECT-scan is made of the specimen in the container with a scanning time of approximately 30 minutes. This is followed by a high resolution CT-scan for anatomical correlation and verification of the I125-seed. If possible, a MRI-scan is acquired at the preclinical scanner for further detailed images of the lesion. Within 1 hour the specimen is delivered at the pathology department for standard histopathological examination.

Study burden and risks

Participation is not associated with significant risks for patients or personnel.

During a normal lumpectomy procedure, patients can receive a low dose of radiation from a ROLL procedure (1mSv), SN procedure (2 mSv), and/or localization with iodine seeds (1 mSv). For this study an extra intravenous injection with 500 MBq Tc99m-SestaMIBI is given, with an additional radiation dose of 4.5 mSv. This is within normal limits for diagnostic procedures and no risks or side-effects are expected. However, women younger than 58 years old are excluded from this study due to the radiation.

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
- Proven breast cancer (DCIS or IDC), cT1 cNx
- Planned to undergo lumpectomy
- Age > 58 years
- IDC: distance nipple to tumour marker > 5cm
- Patients provide written informed consent

Exclusion criteria

- ROLL procedure with Tc-99m
- Administration of other Tc-99m labeled drugs 48 hours prior to surgery(with the exception of Tc-99m for the SN procedure in case of IDC)
- Neo-adjuvant chemotherapy

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-01-2015
Enrollment:	6
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Technescan Sestamibi
Generic name:	99mTc-Sestamibi

Ethics review

Approved WMO Date:	09-07-2014
Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	10-07-2014
Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	26-03-2015
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)
Approved WMO Date:	10-04-2015
Application type:	Amendment
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

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
EudraCT	EUCTR2014-002616-16-NL
CCMO	NL49061.031.14