Validation of (semi)quantitative metabolic SPECT/CT for therapy monitoring in Locally Advanced Breast Cancer: A Feasibility Study

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Primary objective: To assess accuracy and reproducibility of a new and innovative quantitative SPECT image reconstruction technique (QMetrix®) in locally advanced breast cancer. Secondary objectives: To evaluate:a) Hanging breast acquisition mode...

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

Summary

ID

NL-OMON47441

Source
ToetsingOnline

Brief title
Quantitative SPECT/CT in LABC

Condition

- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
Locally advanced breastcancer, Locally advanced Mamma carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: bedrijf,General Electric (GE Healthcare)

Intervention

Keyword: LABC, SPECT/CT, therapy monitoring

Outcome measures

Primary outcome

Endpoint: Validation of 99mTc-sestamibi-based (semi)quantitative metabolic SPECT/CT parameters like standardized uptake value (SUVSPECT), metabolic tumour volume (MTVSPECT), total lesion mitochondrial uptake (TLMU), lesion wash-out (LWO) and tumour to background ratio (T/B), using a quantitative SPECT image reconstruction technique (QMetrix®), for therapy monitoring purposes in patients with LABC

Outcome measures:

- Percentage of BC patients in whom the above mentioned parameters can be technically measured using Q.Metrix® quantitative image reconstruction and SPECT/CT in hanging breast mode;
- Actual measured (semi)quantitative data concerning the above mentioned metabolic tumour parameters;
- Reproducibility analysis of these (semi)quantitative findings.

Secondary outcome

Endpoint:To evaluate hanging breast acquisition mode using SPECT/CT in relation to the following aspects: timing, patient comfort, image quality, (semi)quantitative parameters.

Outcome measures:

- Subjective scoring of patient comfort (patient opinion) and image quality (investigator opinion) on a 3-point scale;
- Percentage of patients in whom the index tumour can be visualised on the early SPECT/CT images, related to lesion diameter/volume;
- Percentage of patients in whom the index tumour can be visualised on the late SPECT/CT images, related to lesion diameter/volume;
- Percentage of patients in whom lesion wash-out can be measured by performing SPECT/CT acquisitions at 5 and 90 min after tracer injection

Endpoint: To determine the feasibility of intratumoural heterogeneity analysis using visual scoring and quantitative textural lesion assessment.

Outcome measures:

- Visual measurement of heterogeneity in breast tumours using a 4-point scale (0: none; 1: mild; 2: moderate; 3: high);
- Percentage of patients in whom quantitative textural lesion assessment can be technically performed, related to tumour size (diameter and volume)

Endpoint: To explore if the (semi)quantitative parameters correlate with the pathological and radiological response to NAC and/or other systemic treatments.

Outcome measures:

- No response to NAC according to histopathology: residual tumour size reduced

< 75% compared to baseline clinical tumour size.

- Response to NAC according to histopathology: residual tumour size reduced

>75% compared to baseline clinical tumour size.

- Histopathological response will be further graded using residual tumour

cellularity.

- Radiological response to NAC according to RECIST criteria.

Study description

Background summary

Breast cancer (BC) is the most common malignancy in women in developed countries. Tumour resistance to neoadjuvant chemotherapy (NAC) is the major cause of therapy failure. Therefore, early prediction of the response to NAC may allow a switch to other drugs in non-responders, avoiding ineffective chemotherapy and leading to more personalized treatment. The role of 18F-FDG PET/CT to monitor NAC response remains unclear and is strongly influenced by breast tumour subtypes. To date, 99mTc-methoxyisobutylisonitrile (99mTc-Sestamibi or MIBI) is the most widely used non-PET radiotracer in BC. MIBI allows in vivo assessment of tumour chemoresistance and appears to early identify those patients who would benefit from alternative treatment. However, monitoring of early response to NAC using MIBI has been limited to planar imaging only (scintimammography and breast-specific gamma imaging [BSGI]) and in relatively small series of patients. Improvements in Single-Photon Emission Computed Tomography (SPECT) software modules, incorporated in the last generation of SPECT/CT devices as currently available at LUMC and Alrijne hospital, enable us to quantitatively study MIBI uptake and retention in tumours including other metabolic parameters and as thus define their role in therapy monitoring.

Study objective

Primary objective: To assess accuracy and reproducibility of a new and innovative quantitative SPECT image reconstruction technique (QMetrix®) in locally advanced breast cancer.

Secondary objectives: To evaluate:
a) Hanging breast acquisition mode using SPECT/CT in relation to the following aspects: timing, patient comfort, image quality, (semi)quantitative parameters.

b) The feasibility of intratumoural heterogeneity analysis using visual scoring and quantitative textural lesion assessment.
c) To explore if the (semi)quantitative parameters correlate with the pathologic response to NAC and/or other systemic treatments.

Study design

Single centre prospective feasibility study
Additional SPECT-CT acquisition in hanging breast mode before and after BSGI (standard care), 5 min and 90 min after intravenous injection of 99mTc-sestamibi.

Study burden and risks

Participation in this study does not impose significant risks for patients or staff. Each patient will receive two additional low dose-CT thorax scans in a total time frame of two hours, which is associated with an additional radiation exposure of 2 x 2.7 mSv = 5.4 mSv. This is within the normal range concerning diagnostic procedures. No side effects or significant risks are expected.
The risk for radiation-induced cancer corresponds to risk category IIb (according to national and European guidelines); This study complies with the requirements associated with this risk category because it is aimed at developing diagnostic techniques for early identification of non-responders in order to timely adjust the therapeutic regimen with the final aim to improve the prognosis of this patient group.

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 * 18 years old
* Proven LABC with at least one index lesion * 2 cm, scheduled for NAC and/or other systematic treatment
* Clinical indication for BSGI

Exclusion criteria

* Pregnancy
* Proven BC with index lesion < 2 cm
* Prior breast surgery, chemotherapy, or radiation therapy
* Clinical or radiological evidence of metastatic lymph nodes (cN+)
* Clinical or radiological evidence of distant metastases (cM+)

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):	22-08-2017
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	26-04-2017
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	03-12-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL60403.058.17

Study results

Date completed:	11-05-2020
Actual enrolment:	19