DETection of Early Radiation-induced Myocardial Injury using cardiac sympathetic inNErvation scintigraphy (DETERMINE)

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We will investigate if irradiation of part of the heart leads to cardiac sympathetic innervation injury and subsequently to radiation induced cardiovascular disease.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coronary artery disorders
Study type	Observational invasive

Summary

ID

NL-OMON38745

Source
ToetsingOnline

Brief title
Detection of radiation-induced myocardial injury after breast irradiation.

Condition

- Coronary artery disorders
- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
cardiac damage, cardiac sympathetic innervation injury

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Haaglanden

Source(s) of monetary or material Support: GE Healthcare,Zie G3a

Intervention

Keyword: breastcancer, irradiation, MIBG

Outcome measures

Primary outcome

The assessment of the cardiac sympathetic system. This will be performed by using 123I-MIBG scintigraphy. The heart-to-mediastinum ratio (H/M ratio) and myocardial washout will be analysed for left- and right-sided breast cancer patients around three years after the radiotherapy treatment.

Secondary outcome

As a secundary endpoint the segmental distribution of the radiofarmacon in the heart will be analysed.

Subjective findings in relation to the results of the MIBG scan of the heart will be described.

Study description

Background summary

Radiotherapy is an independent risk factor for cardiovascular disease in cancer patients. Modern radiotherapy techniques minimize the volume of the heart and major coronary vessels exposed to high radiation doses. Still, some exposure is often not avoidable. Radiation-induced heart disease is caused primarily by inflammatory changes in the microvasculature ultimately leading to perfusion defects and focal ischemia.
Radiation-induced heart disease can be diagnosed non-invasively by myocardial perfusion scintigraphy to assess regional perfusion, wall motion and ejection fraction or by computer tomography to assess the coronary arteries and or calcium burden.
In many clinical circumstances, no structural heart disease can be shown by traditional myocardial perfusion scintigraphy or coronary angiography

investigations. There is strong evidence that cardiac adrenergic innervation is affected in very early stage of coronary artery disease in asymptomatic subjects. In addition, assessment of cardiac sympathetic activity has important prognostic and therapeutic implications in patients with heart disease.
In different cardiovascular diseases, there is growing evidence that, the damage to cardiac sympathetic innervation can precede the alteration in myocardial perfusion. Cardiac sympathetic innervation imaging using 123Iodine-Meta-Iodobenzyl-Guanidine (123I-MIBG) cardiac scintigraphy is one of the few valid techniques available to evaluate sympathetic cardiac diseases. We intend to study the effect of radiotherapy on the cardiac sympathetic innervations using 123I-MIBG cardiac scintigraphy in breast cancer patients about 3 years after radiotherapy.

Study objective

We will investigate if irradiation of part of the heart leads to cardiac sympathetic innervation injury and subsequently to radiation induced cardiovascular disease.

Study design

The cardiac sympathetic function was measured using 123I-MIBG scintigraphy. The cohort consists of breast cancer patients (n=41) treated for whole breast irradiation after (left and right sided) breast conserving surgery in which the degree of vascular damage (CAC -CT) was assessed until three years after radiotherapy.

Study burden and risks

- The Effective Dose Equivalent (EDE) of the total body, as a result of the administered activity of 185 MBq, accounts 3.3mSv.
- Participating to the study will cost the patient 9 hours (including travelling to the specific hospitals)
- If pathology was found in the MIBG scan, action will be taken by the study coordinators
- The results of the study could be of benefit for patients with breast cancer

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

-Histological confirmed adenocarcinoma of the left or right breast
-Operable breast carcinoma (clinically T1-2; N0-1)
-Breast conserving surgery (BCS) (and adequate axillary staging)
-WHO performance: status * 2
- Patients participated in the calcium study [NL18534.098.07 / 07-090]
- Written informed consent

Exclusion criteria

-Histology other than adenocarcinoma
-Distant metastases (including non-ipsilateral lymph node metastases)
-"Locally advanced ("inoperable") breast cancer" (clinically T3-4; N2-3)
-En bloc axillary dissection
-Previous (non surgical) treatment of the breast carcinoma including pre-operative chemotherapy or hormonal therapy
-Neurodegenerative diseases (Multiple systemic atrophy, central autonomic failure)
- Parkinson's disease.
-Male gender
-Pregnancy

Exclusion criteria for the MIBG scan:
- Allergic to previous use of 123I-MIBG.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-08-2014
Enrollment:	41
Type:	Actual

Ethics review

Approved WMO

Date:	20-12-2013
Application type:	First submission
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	NL46465.098.13