MIBG scintigraphy and Strain Echocardiography in the early detection of late cardiovascular effects of (neo)adjuvant breast cancer treatment with docetaxel, doxorubicin and cyclophosphamide (TAC): a pilot study

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1. To detect subclinical cardiovascular damage in adults patients with breast cancer who have completed treatment with TAC at least one year previously at least one year previously, using MIBG scintigraphy, novel echocardiographic techniques and...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Cardiac disorders, signs and symptoms NEC
Study type	Observational invasive

Summary

ID

NL-OMON34932

Source
ToetsingOnline

Brief title
TOXTAC

Condition

- Cardiac disorders, signs and symptoms NEC

Synonym
cardiac injury, cardiotoxicity

Research involving

Human

Sponsors and support

Primary sponsor: Integraal Kankercentrum Oost
Source(s) of monetary or material Support: Ministerie van OC&W,Merck Sharp & Dohme (MSD),Sanofi-aventis

Intervention

Keyword: Breast cancer treatment, Cardiotoxicity, MIBG scintigraphy, Strain Echocardiography

Outcome measures

Primary outcome

left ventricular ejection fraction

Secondary outcome

-clinical symptoms or signs of heart failure (tachycardia, dyspnea, orthopnea,

edema, S3 gallop)

-other echocardiographic parameters to indicate systolic and diastolic

function, left ventricular dimension and left ventricular mass

-electrocardiographical signs of ischemia or arrhytmia

-MIBG uptake below normal

-Troponin-I, NT-pro-BNP, cytokine and adhesion molecule levels above normal

Study description

Background summary

Cardiovascular toxicity is one of the most devastating complications of cancer treatment and can arise during or shortly after treatment, or even several years later. Especially anthracyclines have dose-limiting cardiac toxicity and can result in congestive heart failure and cardiomyopathy years after administration. Few studies have measured cardiovascular toxicity in long-term

breast cancer survivors exposed to anthracycline adjuvant therapy. No data are available on the long-term cardiovascular effect of the combination of docetaxel, doxorubicin and cyclophosphamide. As measurement of left ventricular ejection fraction underestimates cardiac damage, additional strategies for the monitoring of treatment-induced cardiotoxicity need to be explored.

Study objective

1. To detect subclinical cardiovascular damage in adults patients with breast cancer who have completed treatment with TAC at least one year previously at least one year previously, using MIBG scintigraphy, novel echocardiographic techniques and blood biomarkers.
2. To assess the predictive value at baseline of MIBG scintigraphy, novel echocardiographic techniques and blood biomarkers for the development of clinically overt heart failure (New York Heart Association Classification II, III, or IV) five years and ten years after treatment with TAC.
3. To assess the predictive value at baseline of MIBG scintigraphy, novel echocardiographic techniques and blood biomarkers for further deterioration of subclinical cardiotoxicity five years and ten years after treatment

Study design

Non-randomized single centre follow up cohort study

Study burden and risks

Risks associated with participation:
Not applicable, there are no risks associated with participation.

Burden:
It is a burden in terms of time (circa one whole day).

Benefit and group relatedness:
There is no benefit for the participating patients.
There might be a benefit for similar patients in the future:
It is important to detect and prevent cardiac morbidity and mortality in an early stage. This provides the opportunity to timely change to other cancer treatments or other dosage schedules, other combinations, or to add ameliorating agents. This study can also provide significant insights into the mechanisms and pathophysiology of cardiotoxicity caused by the huge number of anti-cancer agents and agents in development.

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

-Female patients with breast cancer, >= 18 years old at the time of breast cancer diagnosis
-(Neo)adjuvant treatment with docetaxel, doxorubicin and cyclophosphamide (TAC) completed minimally one year before inclusion and maximally nine years before.

Exclusion criteria

-Evidence of breast cancer recurrence or metastatic disease
-Evidence of heart disease at the time of breast cancer diagnosis
-Evidence of renal failure at the time of cardiac evaluation
-Pregnant or lactating
-Participation in a research protocol with ionizing radiation within one year before inclusion.

-Evidence of Diabetes Mellitus or Parkinson*s Disease
-Evidence of an MIBG-accumulating tumor

Study design

Design

Study phase:	4
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-11-2010
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO

Date:	22-09-2010
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL31859.091.10