Early detection and prediction of cardiotoxicity in breast cancer patients treated with chemotherapy using the high sensitivity troponin T assay.

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Early detection and prediction of cardiotoxicity in chemotherapy-treated patients with the use of the new high sensitivity troponin t assay.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Heart failures
Study type	Observational invasive

Summary

ID

NL-OMON37774

Source
ToetsingOnline

Brief title
Use of high sensitivity troponin t to detect and predict cardiotoxicity

Condition

- Heart failures
- Breast neoplasms malignant and unspecified (incl nipple)

Synonym
cardiotoxicity, heart failure

Research involving
Human

Sponsors and support

Primary sponsor: Maxima Medisch Centrum

Source(s) of monetary or material Support: Stichting Maxima

Intervention

Keyword: anthracyclines, cardiotoxicity, heart failure, troponin t

Outcome measures

Primary outcome

Relation between hs-TNT values and cardiac dysfunction (measured by left ventricular ejection fraction with echocardiography) after chemotherapy.

Secondary outcome

Secondary objectives of this study are to investigate the relation between the change in hs-TNT values and cardiac function after Ctx.

1. hs-TNT kinetics during Ctx and relation to cardiac function (% LVEF). (delta change within one Ctx cycle, delta change between Ctx cycles, delta change baseline and final hs-TNT value)

2. Detection and prediction of cardiotoxicity (definition: an asymptomatic reduction >10% of the LVEF reaching ,<55%, or a symptomatic reduction >5% of the LVEF reaching <55%) by hs-TNT values (single value or delta changes).

Study description

Background summary

Cardiotoxicity is a serious adverse effect of anticancer drugs, impacting on quality of life and overall survival of cancer patients. Currently, there is increasing evidence that patients previously treated with chemotherapy have an increased cardiovascular risk, with a mortality rate that is about eight-fold that of the general population.

At present, the most frequently used modality for detecting cardiotoxicity is the evaluation of symptoms suggestive ofheart failure, combined with the

periodic non-invasive measurement of left ventricular ejection fraction (LVEF). The current approach includes assessment of baseline cardiac function, before starting CT, and a cardiac surveillance during and after its completion, by the evaluation of LVEF using either echocardiography or multigated acquisition scanning. No consensus- or evidence-based guidelines regarding the cardiac surveillance of cancer patients yet exist. As a consequence, no systematic evaluation for cardiac dysfunction in asymptomatic survivors of cancer is performed, although cardiac morbidity can become apparent even several years after treatment. The most critical limitation of the present approach is that LVEF measurement is a relatively insensitive tool for detecting CT-induced cardiotoxicity at an early stage. This is largely because no considerable change in systolic function occurs until a critical amount of myocardial damage has taken place. Indeed, the weak point is that cardiac damage is usually detected only when a functional impairment has already occurred, precluding any chance of preventing its development. When chemotherapy-induced cardiomyopathy develops, complete recovery of cardiac function occurs inonly 42% of patients, despite optimal pharmacologic therapy.

Study objective

Early detection and prediction of cardiotoxicity in chemotherapy-treated patients with the use of the new high sensitivity troponin t assay.

Study design

This is an observational study, where hs-TNT levels will be measured before, during and after treatment with chemotherapy. The relation of hs-TNT values with cardiac function (measured by echocardiography) will be assessed.

Study burden and risks

Total burden for the patients is 14 venapunctures and 2 times echocardiography.

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 breast cancer patients
-Age between 30-60 years
-18-weeks of chemotherapy-treatment, adjuvant or neo-adjuvant
-Chemotherapy may include: (AC) adriamycin/cyclophosphamide, (FEC) fluorouracil/epiribicin/cyclophosphamide, (TAC) taxotere/ adriamycin/cyclophosphamide
-Ejection fraction > 50%

Exclusion criteria

-Ejection fraction <50%
-previous signs of cardiovascular disease
-kidney dysfunction (eGFR <60 ml/min/1,73m^2).
-previous treatment with anthracyclines

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):	11-01-2013
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	18-09-2012
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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	NL40403.015.12