Endothelial function after anthracycline treatment.

Published: 15-08-2018
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The primary objective is to explore endothelial function in patients before and after treatment with anthracyclines.

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

Summary

ID

NL-OMON46659

Source
ToetsingOnline

Brief title
Endothelial Function after AnthraCycline Treatment (EFACT)

Condition

- Heart failures
- Miscellaneous and site unspecified neoplasms benign

Synonym
Endothelial dysfunction;

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Cancer therapy, Cardiotoxicity, Endothelial dysfunction

Outcome measures

Primary outcome

Endothelial function is measured by reactive hyperemia index (RHI) with a peripheral arterial tonometry (PAT).

Secondary outcome

Demographics, cardiovascular risk factors, medical history, oncological treatment protocol will be obtained from the patient file which is used at the outpatient clinic.

Study description

Background summary

Cardiotoxicity is a feared side-effects of anticancer treatment, and negatively influences the quality of life of patients who benefit from improvements in anticancer treatment. Particularly, anthracyclines and trastuzumab are known for their chance of causing cardiac dysfunction. The underlying mechanisms of cardiotoxicity are partially elucidated. Questions still remain which patients will suffer from this side effect. The role of endothelial dysfunction in cancer therapy-related cardiac dysfunction (CTRCD), has not been fully established yet. This study forms the first step in the research of endothelial dysfunction and cancer therapy-related cardiac dysfunction.

Study objective

The primary objective is to explore endothelial function in patients before and after treatment with anthracyclines.

Study design

Prospective observational study.

Study burden and risks

The measurement of RH-PAT will be performed with the EndoPAT2000, which is a non-invasive and safe diagnostic tool. The main burden for patients is a five minute blood flow occlusion through blood pressure cuff inflation, which gives an unpleasant feeling and might cause slight bruising. The measurement will be performed during a visit to the outpatient clinic. No extra visit or physical examination is required. The study will not affect the treatment of the patients.

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
- Age >=18 years
- Histological proven breast cancer
- Planned treatment: a chemotherapeutic regimen containing anthracyclines.

Exclusion criteria

Patients who are unable to fasten 3 hours prior to the measurement
- Prior treatment with chemotherapy which contained anthracyclines, platinum derivates or bleomycin.
- Prior treatment with high dose chest radiation (i.e. >20Gy)
- Possible confounders on endothelial function
o Current smokers and patients who quitted smoking < 2 years ago.
o Patients with known vascular disease (e.g. symptomatic peripheral or coronary artery disease)
o Patients with Diabetes Mellitus

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-02-2019
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	15-08-2018

Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL62497.041.17