Markers for Acute Chemotherapy induced Cardiovascular changes.

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1. The number of circulating endothelial (progenitor) cells may be reduced during chemotherapy and correlate to the development of cardiovascular disease; 2. Oxidative stress due to chemotherapy may lead to an increased accumulation of Advanced...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28599

Bron
NTR

Verkorte titel
MACC1

Aandoening

testicular cancer

Ondersteuning

Primaire sponsor: Department of Internal Medicine: Division of Medical Oncology, University Medical Center Groningen (UMCG)
Overige ondersteuning: University Medical Center Groningen (UMCG)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The early effects of cisplatin based chemotherapy on the number of circulating endothelial

(progenitor) cells and the accumulation of AGEs, and their correlation with cardiovascular damage.

Toelichting onderzoek

Achtergrond van het onderzoek

Long-term survivors of testicular cancer cured with cisplatin based chemotherapy are at increased risk of developing cardiovascular disease. One of the potential mechanisms behind the development of cardiovascular disease is endothelial damage. We hypothesise that a chemotherapy induced reduction in circulating endothelial (progenitor) cells and accumulation of advanced glycation end products (AGEs) due to chemotherapy induced oxidative stress, might contribute to cardiovascular damage. In this prospective non-randomised cohort study in 50 patients with disseminated testicular cancer, circulating endothelial cells and accumulation of AGEs (reflected by skin autofluorescence) will be measured before, during and after (up to 1 year) cisplatin based chemotherapy and related to cardiovascular changes, as assessed by cardiovascular funcyion tests. With this study we hope to get insight into the underlying mechanisms of chemotherapy induced cardiovascular damage and to find feasible surrogate markers for this damage, which may contribute to the early detection of cardiovascular toxicity and to the design of intervention strategies.

Doel van het onderzoek

1. The number of circulating endothelial (progenitor) cells may be reduced during chemotherapy and correlate to the development of cardiovascular disease;
2. Oxidative stress due to chemotherapy may lead to an increased accumulation of Advanced Glycation End products (AGEs) in blood vessels, contributing to endothelial damage.

Onderzoeksproduct en/of interventie

The number of circulating endothelial cells, endothelial marker proteins and accumulation of AGEs (estimated by measuring skin autofluorescence with an AGE-reader) will be determined before, during and after chemotherapy. Cardiovascular status (intima-media thickness of the carotid artery, baroreflex sensitivity and 24-hour ambulatory blood pressure measurement) will be evaluated before start of chemotherapy, within 4 weeks after completion of chemotherapy and 1 year after start of chemotherapy.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients with disseminated testicular cancer who will be treated with cisplatin based chemotherapy;
2. Age 18-50 years at start of treatment;
3. Written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Medical history of cardiovascular disease;
2. Known renal disease or estimated glomerular filtration rate (GFR) < 60 ml/min (using Cockcroft-Gault formula).

Onderzoeksopzet

Opzet

Type: Interventie onderzoek

Onderzoeksmodel:	Anders
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	16-05-2006
Aantal proefpersonen:	50
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	19-05-2006
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL627
NTR-old	NTR686
Ander register	: N/A
ISRCTN	ISRCTN54551960

Resultaten

Samenvatting resultaten
N/A