Blood- and urinary levels of different carnitine-esters during administration of oxaliplatin based chemotherapy

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We hypothesize that depletion of carnitine occurs during infusion of oxaliplatin, due to increased renal loss. This secondary carnitine deficiency may contribute to the development of CIPN.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON21217

Bron
Nationaal Trial Register

Verkorte titel
-

Aandoening

Carnitine metabolism and carnitine deficiëncy
Interaction of oxaliplatin chemotherapy with carnitine
Chemotherapy induced peripheral neuropathy

Ondersteuning

Primaire sponsor: Máxima Medisch Centrum
Overige ondersteuning: Alfasigma BV Nederland

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- To evaluate the course of plasma- and urinary carnitine levels of all carnitine esters during the first cycle of treatment with oxaliplatin-based chemotherapy:
Plasma and urinary concentrations of different carnitine-esters before, during and right after administration of oxaliplatin-based chemotherapy

Toelichting onderzoek

Achtergrond van het onderzoek

Chemotherapy-induced peripheral neuropathy (CIPN) is a common, dose-limiting side effect of cytotoxic agents that can lead to decreased quality of life and suboptimal treatment, which can lead to decreased survival. Currently, there are no effective prophylactic and therapeutic options available. Research has been done to study the effect of carnitine, but results are contradictory probably due to severe heterogeneity between different studies and inadequate administration of carnitine. We hypothesize that depletion of carnitine occurs during infusion of oxaliplatin, due to increased renal loss. This might contribute to the development of CIPN. The primary objective of this study is to investigate the course of plasma- and urinary levels of different carnitine-esters during IV administration of oxaliplatin. A prospective observational study will be performed. All patients planned to start with oxaliplatin-based chemotherapy at the Máxima Medical Centre in Veldhoven/Eindhoven are eligible for participation in this study.

Doel van het onderzoek

We hypothesize that depletion of carnitine occurs during infusion of oxaliplatin, due to increased renal loss. This secondary carnitine deficiency may contribute to the development of CIPN.

Onderzoeksopzet

Draw blood at baseline, 5 minutes, 60 minutes, 120 minutes and 180 minutes

Collect urine at baseline and 180 minutes

Onderzoeksproduct en/of interventie

No intervention/controls.

For measurements: drawing blood and collecting urine.

Contactpersonen

Publiek

L. Verdonschot
[default]
The Netherlands

Wetenschappelijk

L. Verdonschot
[default]
The Netherlands

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Written informed consent

2. Age >18 years

3. Start treatment with oxaliplatin-based chemotherapy

4. Understanding the Dutch language

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Patients with known primary carnitine deficiency (congenital)

2. Patients on haemodialysis or peritoneal dialysis

3. Patients with epilepsy

4. Current treatment with valproic acid or zidovudine

5. Current use of carnitine supplements or use of carnitine supplements in the past 3 months

6. Pre-existent neuropathy or comorbid disorder causing neuropathy

7. Previous treatment with neurotoxic chemotherapy

8. Participation in an intervention study on CIPN (e.g. Frozen Gloves)

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2018
Aantal proefpersonen:	10
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL7114
NTR-old	NTR7319
Ander register	NL65037.015.18 : ABR (CCMO)

Resultaten