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

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON21217

Source
NTR

Brief title
-

Health condition

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

Sponsors and support

Primary sponsor: Máxima Medisch Centrum
Source(s) of monetary or material Support: Alfasigma BV Nederland

Intervention

Outcome measures

Primary outcome

- 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

Secondary outcome

- To gain insight in patient factors such as lifestyle, diet and comorbidities that can influence baseline carnitine levels in cancer patients:

Length and body weight, information about diet, nicotine- and alcohol consumption habits, comorbidities, type of cancer, cancer stage, chemotherapy regimen, history of chemotherapy use.

Study description

Background summary

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.

Study objective

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.

Study design

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

Collect urine at baseline and 180 minutes

Intervention

No intervention/controls.

For measurements: drawing blood and collecting urine.

Contacts

Public
L. Verdonschot
[default]
The Netherlands
Scientific
L. Verdonschot
[default]
The Netherlands

Eligibility criteria

Inclusion criteria

1. Written informed consent

2. Age >18 years

3. Start treatment with oxaliplatin-based chemotherapy

4. Understanding the Dutch language

Exclusion criteria

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)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2018
Enrollment:	10
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL7114
NTR-old	NTR7319
Other	NL65037.015.18 : ABR (CCMO)

Study results