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

Published: 06-09-2018
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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.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON46342

Source
ToetsingOnline

Brief title
Carnitine levels during oxaliplatin infusion

Condition

- Other condition
- Protein and amino acid metabolism disorders NEC

Synonym
Defeciency/lack of/reduction of concentration of carnitine (an amino acid or half-vitamin) during/caused by treatment with chemotherapy (oxaliplatin)

Health condition

Carnitine metabolisme en excretie, deficiëntie, interactie met chemotherapie (oxaliplatin)

Research involving
Human

Sponsors and support

Primary sponsor: Maxima Medisch Centrum
Source(s) of monetary or material Support: Alfasigma (subsiding party) zorgt voor de vergoeding van de analyse van de labsamples,Alfasigma Nederland B.V.

Intervention

Keyword: carnitine, oxaliplatin

Outcome measures

Primary outcome

The entire carnitine spectrum in plasma will be measured using a precursor ion

scan. Urinary analysis will be done to measure the concentration of L-carnitine

in urine.

Secondary outcome

Not applicable

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.

Study objective

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.

Study design

A prospective observational study will be performed.

Study burden and risks

Risks of participation in this study are limited, since only blood is drawn and urine is collected. Drawing of blood occurs a lot in daily practice, and despite the fact that complications are known, occurrence is rare.

Contacts

Public
Maxima Medisch Centrum

De Run 4600
Veldhoven 5504 DB
NL
Scientific
Maxima Medisch Centrum

De Run 4600
Veldhoven 5504 DB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

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 invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-03-2019
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	06-09-2018
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	NL65037.015.18