The effect of intravenous L-carnitine supplementation during oxaliplatin based chemotherapy on blood- and urinary levels of carnitine

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Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON48693

Source
ToetsingOnline

Brief title
Pilot carnitine supplementation during oxaliplatin infusion

Condition

- Other condition
- Lipid metabolism disorders

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

Health condition

Carnitine metabolisme, 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 Nederland B.V.,Alfasigma Nederland B.V. (subsiding party) zorgt voor vergoeding van de kosten (laboratorium en apotheek)

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 and can be prevented by infusion of levocarnitine .

Study objective

The primary objective of this study is to evaluate the course of plasma- and urinary levels of carnitine and all carnitine esters during the first cycle of treatment with oxaliplatin-based chemotherapy and intravenous carnitine supplementation. The secondary objective is to evaluate if the chosen route and dose of carnitine supplementation are adequate to prevent a carnitine deficiency.

Study design

An open pilot study will be performed.

Intervention

Patients will receive levocarnitine 2 gram intravenously, before start of the oxaliplatin-based chemotherapy. Blood and urinary samples will be collected during administration of the chemotherapy.

Study burden and risks

Risks of participation in this study are limited, since only blood is drawn and an endogenous nutrient is infused. Drawing of blood occurs a lot in daily practice, and despite the fact that complications are known, these are not serious and occurrence is rare. Infusion of carnitine is generally considered safe, with nausea and diarrhoea being the only known minor side effect. This could also be caused by chemotherapeutics in this study, profylactic treatment and supportive care will be supplied as usual care.

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

1. Written informed consent
2. Age >18 years
3. Start treatment with oxaliplatin-based chemotherapy
4. Understanding the Dutch language

Exclusion criteria

1. No written informed consent
2. Patients with known primary carnitine deficiency (congenital)
3. Patients on haemodialysis or peritoneal dialysis
4. Patients with epilepsy
5. Current treatment with valproic acid or zidovudine
6. Current use of carnitine supplements or use of carnitine supplements in the past 3 months
7. Pre-existent neuropathy or comorbid disorder causing neuropathy
8. Previous treatment with neurotoxic chemotherapy
9. Participation in an intervention study on CIPN (e.g. Frozen Gloves)
6. Current use of carnitine supplements or use of carnitine supplements in the past 3 months, 7. Pre-existent neuropathy or comorbid disorder causing neuropathy, 8. Previous treatment with neurotoxic chemotherapy, 9. Participation in an intervention study on CIPN (e.g. Frozen Gloves)

Study design

Design

Study phase:	2
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2019
Enrollment:	10
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	carnitene
Generic name:	levocarnitine
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO

Date:	06-11-2019
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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
EudraCT	EUCTR2018-000485-11-NL
CCMO	NL66001.028.18