Acute peripheral neuropathy in patients treated with oxaliplatin; Is it possible to decrease the complaints?

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Main object Is there a reduction of the acute peripheral neuropathy complaints of patients with advanced or metastatic colorectal cancer due to the infusion of heated oxaliplatin?Does the quality of life of these patients improve?Secondary objectThe...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Peripheral neuropathies
Study type	Interventional

Summary

ID

NL-OMON33428

Source
ToetsingOnline

Brief title
Effect of heated oxaliplatin on acute peripheral neuropathy, a pilot study

Condition

- Peripheral neuropathies

Synonym
neuropathy

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: manager zorg eenheid geneeskunde

Intervention

Keyword: acute, neuropathy, oxaliplatin, peripheral

Outcome measures

Primary outcome

Main study parameters/endpoints:

Decrease of the acute peripheral neuropathy complaints with 1 point or more on

the four points scale of the Total Neuropathy Score.

Changes in quality of life (cancer related and symptom related) in the period

after infusion of heated oxaliplatin in comparison with the period after

infusion of oxaliplatin on roomtemperature.

Secondary outcome

Secondairy endpoint:

Respons rate by CT scan en changes of CEA (tumormarker)

Study description

Background summary

Rationale:
Despite of the common preventive medication with calcium and magnesium, eightyfive to ninety percent of the patients treated with oxaliplatin for a colorectal carcinoma, will suffer from an acute peripheral neuropathy. These complaints disable patients temporarily and therefore reduce their quality of live during the treatment with chemotherapy.

Study objective

Main object
Is there a reduction of the acute peripheral neuropathy complaints of patients with advanced or metastatic colorectal cancer due to the infusion of heated oxaliplatin?
Does the quality of life of these patients improve?

Secondary object
The evaluation of the effectivity of the treatment.

Study design

Study design:
A pilot study in 15 patients.

Intervention

Intervention:
Oxaliplatin will be heated to a temperature of 36 degrees celsius during the 2-hours infusion period, irrespective the standard prophylaxis with magnesium and calcium.

Study burden and risks

Before entering the study an assessment of acute peripheral neuropathy will be carried out on two moments.
If acute peripheral neuropathy is diagnosed, patients will enter the study.
During the second, third and fourth cycle of the chemotherapeutical regime the Total Neuropathy Score examination will be carried out on three moments.
Quality of life will be measured by the EORTC-QLQ-C30 and the QLQ-CIPN20 questionaire on 2 moments of each course.
If acute peripheral neuropathy is not diagnosed patients will not enter the study.
There is no physical risk or physiological discomfort to expect from the infusion of heated oxaliplatin.

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

Patients with advanced or metastatic colorectal carcinoma
Treatment with oxaliplatin containing regime
Acute peripheral neuropathy complaints after the first course with oxaliplatin
Living within a radius of 30 km from the hospital
Good understanding of the Dutch language

Exclusion criteria

Presence of diabetes mellitus, renal failure, alcoholism, vitamin B 12 deficiency, other neoplasm or HIV.
Previous treatment with a neurotoxin cytostatic drug.
Already existing peripheral neuropathy

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-03-2010
Enrollment:	15
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO Date:	15-10-2009
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	08-03-2010
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 19943
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL29016.100.09
OMON	NL-OMON19943