

# 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 object The...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Peripheral neuropathies
<b>Study type</b>	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

Secondary endpoint:

Response rate by CT scan and 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 life 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 questionnaire 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**

### **Public**

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### **Scientific**

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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: NTR  
Title:

## In other registers

Register	ID
CCMO	NL29016.100.09
OMON	NL-OMON19943