Effect van verwarmde oxaliplatin op acute perifere neuropathie klachten bij patienten die aanvullend of voor een gevorderde of uitgezaaide darmkanker behandeld worden met oxaliplatin houdende chemotherapie.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON19943

Source
Nationaal Trial Register

Brief title
Neuroxa studie

Health condition

acute peripheral neuropathy
colorectal cancer
oxaliplatin induced complaints

Sponsors and support

Primary sponsor: non
Source(s) of monetary or material Support: non

Intervention

Outcome measures

Primary outcome

1. Decrease of the acute peripheral neuropathy complaints with 1 point or more on the four points scale of the Total Neuropathy Score;

2. 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

Respons rate by CT scan and changes of CEA (tumormarker).

Study description

Background summary

Rationale:

Despite of the common preventive medication with calcium and magnesium, sixty to seventy 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.

Objectives:

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:

A pilot study in 15 patients.

Study population:

Patients treated adjuvant or palliative with oxaliplatin for a colon-rectal carcinoma who suffer from an acute peripheral neuropathy after the first treatment in het St. Antonius hospital of Nieuwegein/Utrecht (The Netherlands).

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.

Main study parameters/endpoints:

Changes in the acute peripheral neuropathy complaints.
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.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

Before entering the study 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.
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.

Study objective

Does heated oxaliplatin reduce the acute peripheral neuropathy complaints in patient with a colorectal carcinoma.

Study design

1. Baseline TNS after course one with oxaliplatin;

2. Just before, 48 hours and one week after two courses with heated oxaliplatin and one course with oxaliplatin on room temperature;

3. CEA, CT scans at baseline, 3 and 6 months after start chemotherapy.

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.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients treated adjuvant or palliative with oxaliplatin for a colon-rectal carcinoma who suffer from an acute peripheral neuropathy after the first treatment with oxaliplatin containing regime;

2. Living within a radius of 30 km from the hospital;

3. Good understanding of the Dutch language.

Exclusion criteria

1. Presence of diabetes mellitus, renal failure, alcoholism, vitamin B 12 deficiency, other neoplasm or HIV;

2. Previous treatment with a neurotoxin cytostatic drug;

3. Already existing peripheral neuropathy.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-03-2010
Enrollment:	16
Type:	Anticipated

Ethics review

Positive opinion

Date:	03-04-2011
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 33428
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL2700
NTR-old	NTR2837
CCMO	NL29016.100.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON33428

Study results

Summary results
N/A