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.

Gepubliceerd: 03-04-2011 Laatst bijgewerkt: 19-03-2025

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

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON19943

Bron
Nationaal Trial Register

Verkorte titel
Neuroxa studie

Aandoening

acute peripheral neuropathy
colorectal cancer
oxaliplatin induced complaints

Ondersteuning

Primaire sponsor: non
Overige ondersteuning: non

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

St. Antonius Ziekenhuis
Koekoekslaan 1
A. Verbeek
Nieuwegein 3430 EM
The Netherlands
+31 (0)88 3203000

Wetenschappelijk

St. Antonius Ziekenhuis
Koekoekslaan 1
A. Verbeek
Nieuwegein 3430 EM
The Netherlands
+31 (0)88 3203000

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	15-03-2010
Aantal proefpersonen:	16
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	03-04-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 33428
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A