Decreasing acute peripheral neuropathy in patients treated with Oxaliplatin (heated oxaliplatin versus oxaliplatin on room temperature)

Published: 03-04-2009
Last updated: 05-05-2024

Objective: Main object Does warming of oxaliplatin, during the two hours infusion period, reduces the acute peripheral neuropathy complaints of patients with a colo-rectal tumor more than 50% in comparison with the standard treatment?Secondary…

Ethical review	Not approved
Status	Will not start
Health condition type	Peripheral neuropathies
Study type	Interventional

Summary

ID

NL-OMON32647

Source
ToetsingOnline

Brief title
heated oxaliplatin versus oxaliplatin on room temperature

Condition

- Peripheral neuropathies

Synonym
acute peripheral neuropathy

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis

Source(s) of monetary or material Support: eigen middelen zorgeenheid geneeskunde

Intervention

Keyword: acuut, neuropathy, Oxaliplatin, peripheral

Outcome measures

Primary outcome

Main study parameters/endpoints:

About 40% of the patients treated with oxaliplatin will suffer from acute peripheral neuropathy. This study will be successful if the complaints of patients in the intervention group can be reduced with 50%.

Secondary outcome

Secondary objects

Is there a difference in severity of acute peripheral neuropathy and quality of life between the intervention and the standard group of patients?

Is there a correlation between the severity of acute peripheral neuropathy and the quality of life in both groups

Study description

Background summary

Rationale:
Forty percent of the patients who will be treated with oxaliplatin for a colo-rectal carcinoma will suffer from an acute peripheral neuropathy, in spite of the preventive medication. This study wants to answer the question if warming up oxaliplatin gives a relief of these complaints of patients.

Study objective

Objective:
Main object

Does warming of oxaliplatin, during the two hours infusion period, reduces the acute peripheral neuropathy complaints of patients with a colo-rectal tumor more than 50% in comparison with the standard treatment?
Secondary objects
Is there a difference in severity of acute peripheral neuropathy and quality of life between the intervention and the standard group of patients?
Is there a correlation between the severity of acute peripheral neuropathy and the quality of life in both groups?

Study design

Study design:
A randomised blinded Clinical Trial, blinded for the nurses who carry out the neurologic examinations and for those who carry out the analysis.

Intervention

Intervention:
Patients in the intervention group (arm A) receive warmed oxaliplatin, during a 2-hours infusion (temperature of 360 Celsius), patients in the control group (arm B) receive oxaliplatin, during a 2-hours infusion (room temperature) and receive the usual care which exists out of warm packages when patients suffer from cramps or pain in the infusion arm, if necessary the infusion time will be prolonged to 6 hours.

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
Patients will undergo a neurologic examination (TNSc) just before (T0), within 24-48 hours (T1) and 7 days (T2) after two infusions of oxaliplatin. The examination on T0 will take place in the hospital just before the infusion. The examination on T1 and T2 will take place at the patients home by the trained nurse to minimize the burden.
Patients will register their experienced peripheral neuropathy complaints and quality of life by the QlQ30 and QlQ-CIPN20 questionnaire on T0 and T2.

There is no physical risk or physiological discomfort to expect from the infusion of warmed oxaliplatin. Oxaliplatin will stay stabile if it is warmed to 41o Celsius, so this intervention will not interfere with the treatment results.

Contacts

Public
Sint Antonius Ziekenhuis

Koekoekslaan 1
3430 EM Nieuwegein
Nederland
Scientific
Sint Antonius Ziekenhuis

Koekoekslaan 1
3430 EM Nieuwegein
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Age 18 - 70 years
Treated with Oxaliplatin mono or in combination with other chemotherapeutical drugs or angiogenesis inhibitors.
Adjuvant or palliative treatment for colorectal carcinoma
Patients live within a radius of 30 km from the hospital

Exclusion criteria

Patients with diabetes mellitus, renal failure, alcoholism, vitamin B 12 deficiency, other neoplasm and HIV.
Patients who are treated in an early stage, with a cytostatic with a neurotoxicity profile.

Patients with an already existing peripheral neuropathy
Patients with congenital peripheral neuropathy

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	30
Type:	Anticipated

Ethics review

Not approved

Date:	03-04-2009
Application type:	First submission
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

No registrations found.

In other registers

Register	ID
CCMO	NL26272.100.08