chronic cisplatin induced nephropathy

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to determine the prevalence and significance of chronic nephrotoxic effects of cisplatin therapy by 1) identifying patients with chronic cisplatin nephrotoxicity and 2) reviewing their QoL. Eventually, this could improve care in these patients

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Nephropathies
Study type	Observational invasive

Summary

ID

NL-OMON43000

Source
ToetsingOnline

Brief title
chronic cisplatin induced nephropathy

Condition

- Nephropathies

Synonym
cisplatin nephropathy, kidney injury due to cisplatin

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: subsidie college zorgverzekeringen

Intervention

Keyword: cisplatin, kidney injury, nephropathy, tubulopathy

Outcome measures

Primary outcome

number of patients with chronic cisplatin nephropathy (chronic kidney injury

defined as a reduced GFR or biochemical signs of tubulopathy).

Secondary outcome

Quality of life in patients with nephropathy versus no signs of nephropathy

Study description

Background summary

Cisplatin is the most widely used agent in the chemotherapy of cancer. The chief limit to efficacy is its toxicity (nephrotoxicity, neurotoxicity and ototoxicity). Cisplatin-induced nephropathy or chronic kidney injury can present as a decreased glomerular filtration rate (GFR), and tubulopathy leading to the loss of electrolytes such as magnesium. Most reports have studied the short term effects of cisplatin therapy only (acute kidney injury and initial hypomagnesemia). The long term nephrotoxic effects of cisplatin however could be very relevant as chronic hypophosphatemia, hypomagnesemia and a decreased GFR result in a decreased quality of life and increased mortality. The timely diagnosis and therefore treatment of chronic cisplatin nephrotoxicty could improve quality of life, morbidity and mortality of patients who have been treated with cisplatin.

Study objective

to determine the prevalence and significance of chronic nephrotoxic effects of cisplatin therapy by 1) identifying patients with chronic cisplatin nephrotoxicity and 2) reviewing their QoL. Eventually, this could improve care in these patients

Study design

cross-sectional study in which all patients who received cisplatin therapy more than one year ago and visit the outpatient oncology clinic will be included. Blood and urine investigations will be performed and a quality of life questionnaire is taken after the patient has given his/her informed consent.

Study burden and risks

There is only a small risk accompanying the withdrawal of blood in those patients in whom otherwise blood was not taken.

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

age * 18 years old
last gift cisplatin more than 1 year ago
all doses of cisplatin
all original oncological diagnoses

Exclusion criteria

none

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-04-2017
Enrollment:	500
Type:	Actual

Ethics review

Approved WMO

Date:	12-01-2017
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL57381.091.16