The nephroprotective effect of short hydration during cisplatin treatment in head and neck cancer patients.

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To evaluate the incidence of CIN during cisplatin 40mg/m2 Q1W chemotherapy in patients with head and neck cancer and establish whether SH is superior to LH during cisplatin chemotherapy in reducing the incidence of AKI grade>=1.Secondary...

Ethical review	Approved WMO
Status	Completed
Health condition type	Miscellaneous and site unspecified neoplasms benign
Study type	Interventional

Summary

ID

NL-OMON50989

Source
ToetsingOnline

Brief title
Shortcis

Condition

- Miscellaneous and site unspecified neoplasms benign
- Renal disorders (excl nephropathies)

Synonym
kidney damage, Nephrotoxicity

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Acute Kidney Injury, Cisplatin, Nephrotoxicity, Short hydration

Outcome measures

Primary outcome

The incidence acute kidney injury (AKI) grade >= 1 according to CTCAE v4.0 criteria during cisplatin 40mg/m2 Q1W chemo radiation in patients with head and neck cancer using a long hydration scheme compared to patients using a short hydration scheme.

Secondary outcome

- To examine the incidence of AKI grade 1, grade 2, grade 3, grade 4 and grade 5 according to CTCAE v4.0

- To examine the incidence of AKI according to RIFLE criteria and KDIGO criteria

- To examine the incidence of creatinine increased any grade according to baseline criteria according CTCAE v4.0

- To examine the incidence of creatinine increased any grade according to Upper Limit of Normal (ULN) criteria according CTCAE v4.0

- To examine the incidence of chronic kidney disease (CKD) any grade according to CTCAE v4.0 six months after the last cisplatin cycle

- To examine the change in eGFR due to cisplatin chemo radiation. By examining the difference in eGFR (CKD-EPI) before cisplatin treatment (pre-treatment eGFR) and the eGFR after the last cisplatin cycle (post-treatment eGFR)

- To examine the effect of hydration duration on the relative dose intensity of administered cisplatin.

- To examine the safety of a short hydration scheme by examining the incidence

of hospitalizatons

Study description

Background summary

Cisplatin based chemotherapy remains the main treatment for head and neck cancer patients. Although highly effective cisplatin efficacy is often limited by toxicity. Cisplatin induced nephrotoxicity (CIN) remains the main dose limiting toxicity despite numerous preventive interventions. Extensive hydration prior- and post cisplatin infusion is one of the interventions to prevent nephrotoxicity. Its efficacy in reducing CIN is well established. The optimal duration of hydration is however still debated.
During the last decades numerous publications have reported about the feasibility of a short hydration scheme during cisplatin chemotherapy. Some publications have even shown that short hydration during cisplatin chemotherapy might even be more effective in preventing nephrotoxicity than long hydration. Most of these publications are however limited by their design as they consist of non-randomized single arm studies, retrospective studies or prospective studies with historical controls. Data from randomized controlled clinical trials are still lacking.
Besides possible better nephroprotective effects, short hydration has other clear benefits over long hydration as well. Short hydration would enable outpatient treatment and reduced treatment burden for patients, optimizing quality of life and reducing healthcare costs.
Therefore we shall conduct a prospective randomized controlled trial to examine superiority of a short hydration (SH) scheme versus and long hydration (LH) scheme during Cisplatin treatment in head and neck cancer patients with regard to the incidence of CIN expressed as the clinically significant endpoint Acute Kidney Injury.

Study objective

To evaluate the incidence of CIN during cisplatin 40mg/m2 Q1W chemotherapy in patients with head and neck cancer and establish whether SH is superior to LH during cisplatin chemotherapy in reducing the incidence of AKI grade>=1.
Secondary objectives are to determine differences in average relative dose intensity and the difference in the incidence of acute kidney injury grade 1, grade 2, grade 3, grade 4 and grade 5 as per Common Terminology Criteria for Adverse Events; CTCAE v4.0, incidence of hospitalization due toxicity.

Study design

A prospective, unblinded, single center, randomized controlled clinical trial in which the superiority of short hydration versus long hydration is examined regarding the incidence of Acute Kidney Injury grade >=1

Intervention

Patients will receive standard care cisplatin chemo radiation therapy. Prior to treatment, patients will be randomized over an arm in which the cisplatin is administered using a long hydration regime or an experimental arm in which patients are given cisplatin using a short hydration regimen.

Study burden and risks

We see the risk and burden as negligible. Patients do not have to bear additional burdens compared to their standard care treatment.

For future analysis, an extra bloodsample (10 ml) and a portion of urine will be taken per study visit. In addition, patients in the study will be required to attend one additional follow-up visit 3 months after the last treatment with cisplatin. During this follow-up visit, one extra blood sample (10 ml) and a portion of urine will also be taken for future analysis.

The risk, although we do not expect this, is that more nephrotoxicity will occur in the short hydration arm. We will address this risk with an interim analysis.

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;
- Newly diagnosed head and neck cancer with a standard of care indication for cisplatin 40 mg/m2
Q1W chemo radiation treatment
- Written informed consent according to the International Council for Harmonisation-Good clinical
practice (ICH-GCP) and national / local regulations
- Ability to return to the Erasmus MC Cancer Institute for adequate follow-up

Exclusion criteria

- Prior treatment with cisplatin.
- The presence of clinically relevant drug interactions according to the current SmPC
- The presence of clinically relevant contra-indications according to the current SmPC
- Hypersensitivity towards cisplatin or any of the excipients
- Pregnancy or lactation
- Chronic kidney disease
- Baseline eGFR < 60 ml/min

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	04-03-2021
Enrollment:	226
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Platinol
Generic name:	Cisplatin
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	16-02-2021
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO Date:	23-02-2021
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
EudraCT	EUCTR2020-003890-23-NL
CCMO	NL75382.078.20