Long versus short hydration during cisplatin
based chemotherapy

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Short hydration during cisplatin chemo radiation is significantly more effective than long hydration in preventing acute kidney injury

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

Samenvatting

ID

NL-OMON21238

Bron
NTR

Verkorte titel
ShortCis

Aandoening

Head and neck cancer

Ondersteuning

Primaire sponsor: Erasmus MC
Overige ondersteuning: Erasmus MC

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Creatinine Increased grade 2 or higher (baseline criteria) according to CTCAE v5.0

Toelichting onderzoek

Achtergrond van het onderzoek

Cisplatin based chemotherapy is frequently used in the treatment of 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, like extensive hydration prior- and post cisplatin infusion. Its efficacy in reducing CIN is well established (1), although the optimal duration of hydration is still debated. According to the SPC of cisplatin patients receiving cisplatin should receive hydration pre- and post-hydration for a total of 12-24 hours (2).
During the last decades numerous publications have reported about the feasibility of shorter hydration schemes (4-6 hours) during cisplatin chemotherapy (3-9). Some publications have even shown that short hydration (SH) during cisplatin chemotherapy might even be more effective in preventing nephrotoxicity than long hydration (LH) (10-14). 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. Despite this limited evidence, SH schemes are increasingly adopted as part of standard of care cisplatin treatment. This is because SH has considerable advantages over LH as it could shorten patients stay in hospital and enable outpatient instead of inpatient treatment. This could lead to reduced treatment burden for patients, optimized quality of life and reduced healthcare costs. In order to establish the nephroprotective superiority of SH over LH a prospective, open label, randomized controlled trial will be conducted.

Doel van het onderzoek

Short hydration during cisplatin chemo radiation is significantly more effective than long hydration in preventing acute kidney injury

Onderzoeksopzet

Baseline screening 1st cycle 2nd cycle 3rd cycle 4th cycle 5th cycle 6th cycle 7th cycle Last study visit (3 months after last cycle)
Medical history X
In- / exclusion criteria X
Provide Information about the study X
Written informed consent X
Hematology and blood chemistry X X X X X X X X
Urine sample collection X X X X X X X X
Cisplatin chemotherapy X X X X X X X

Onderzoeksproduct en/of interventie

Short hydration protocol during cisplatin chemo radiation

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Age ≥18 years;
All patients with diagnosed head and neck cancer with a standard of care indication for chemo radiation with weekly cisplatin 40 mg/m2 (CHEMORAD) treatment.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Prior treatment with cisplatin.
Unable to give written informed consent according to the International Council for Harmonisation-Good clinical practice (ICH-GCP) and national / local regulations

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek

Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-04-2021
Aantal proefpersonen:	226
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	10-02-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9291

Register	ID
Ander register	METC EMC : METC 2020-0925

Resultaten