Low dose cisplatin in sarcopenic head and neck cancer patients

Gepubliceerd: 25-01-2021 Laatst bijgewerkt: 19-03-2025

We hypothesize that in LA-HNSCC patients with low SMM, receiving weekly low dose cisplatin concurrent RT have a higher compliance rate to planned chemotherapy scheme compared to patients receiving the three-weekly scheme, resulting in a higher...

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

Samenvatting

ID

NL-OMON25064

Bron
NTR

Verkorte titel
CISLOW

Aandoening

Locally advanced head and neck squamous cell carcinoma

Ondersteuning

Primaire sponsor: University Medical Center Utrecht
Overige ondersteuning: ZonMw

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome parameter is compliance (non CDLT) rate to the proposed cisplatin scheme. Compliance to chemotherapy is defined as the absence of CDLT. CDLT is defined as

any toxicity resulting in a cisplatin dose-reduction of ≥50%, a postponement of treatment of ≥4 days or a definite termination of cisplatin after the first or second cycle of therapy.

Toelichting onderzoek

Achtergrond van het onderzoek

In this multicenter prospective low-intervention clinical trial the compliance of weekly low dose compared to three-weekly high dosecisplatin with concurrent RT in seventy LA-HNSCC patients with low SMM will be investigated. To assure the inclusion of seventy low SMM patients, a total of 129 LA-HNSCC patients should be included according to the incidence rate of low SMM in this population. The goal of this study is to treat patients more effective and safer. Patients with low SMM will be randomised between two schemes, weekly low dose cisplatin versus three-weekly high dose cisplatin. Both schemes are considered as standard of care in which the goal is to obtain a equivalent cumulative dosage. Other participating centers will be added in an amendment.
Cumulative cisplatin dose, time to recurrence, 2-year overall survival, costs, quality of life and patient’s preference will be assessed.Toxicities will be recorderd using the Common Terminology Criteria for Adverse Events (CTCAE) criteria. Quality of life will be measured using European Organisation for Research and Treatment of Cancer (EORTC) questionnaires and will be send by e-mail.When the patient or treating physician ask for a non-digital questionnaire, the questionnaires will be send via post and answers will be put into Castor by the investigator. A cost-effectiveness analysis will be performed. Semi-structured interviews will be done, toassess patients' preferences.

Doel van het onderzoek

We hypothesize that in LA-HNSCC patients with low SMM, receiving weekly low dose cisplatin concurrent RT have a higher compliance rate to planned chemotherapy scheme compared to patients receiving the three-weekly scheme, resulting in a higher cumulative dosage and possibly improved outcomes.

Onderzoeksopzet

Before and during chemoradiotherapy and 2 years of follow-up with specific time points being 3, 6, 12 and 24 months post therapy for sending of questionnaires and also these months plsu 18 months post therapy for data collection.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- considered eligible and planned for primary cisplatin CRT by treating physician;
- eighteen years of age or older;
- sufficient understanding of Dutch and medical consequences to give informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- mentally disabled or patients with significantly altered mental status that would prohibit understanding and giving informed consent;
- a history of bilateral lymph node dissection in the neck and no available (PET-)CT scan of the third lumbal vertebra;
- an absolute contraindication for cisplatin as defined by the treating physician, including relevant pre-existingkidney insufficiency, clinically apparent vascular disease (for example claudicatio intermittens), clinically relevant perceptive deafness, serious neuropathy and poor performance score.
- an absolute contraindication for high dose three-weekly cisplatin 100 mg/m2 as defined by the treating physician;
- interval between diagnostic scan and planned CRT >2 months;
- cisplatin CRT planned as non-primary or induction treatment.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	29-07-2021
Aantal proefpersonen:	129
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:	25-01-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 56152
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9217
CCMO	NL76533.041.21
OMON	NL-OMON56152

Resultaten