Low dose cisplatin in sarcopenic head and neck cancer patients

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25064

Source
NTR

Brief title
CISLOW

Health condition

Locally advanced head and neck squamous cell carcinoma

Sponsors and support

Primary sponsor: University Medical Center Utrecht
Source(s) of monetary or material Support: ZonMw

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

Secondary outcome parameters are adverse events/toxicity, cumulative cisplatin dose, time to recurrence, 2-year overall survival,costs, quality of life and patient’s preference. The main oncological outcome parameters are time to recurrence and survival. Clinically relevant treatment related toxicity parameters, including specific toxicity that results in significant (grade 3 or 4) toxicity, treatment de-escalation or termination, will be recorded by the treating medical oncologist. Toxicity will be scored according to theCommon Terminology Criteria for Adverse Events (CTCAE) guidelines, v5.0.

Study description

Background summary

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.

Study objective

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.

Study design

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.

Contacts

Public
UMC Utrecht
Anouk Schaeffers

+31 88 75 691 14
Scientific
UMC Utrecht
Anouk Schaeffers

+31 88 75 691 14

Eligibility criteria

Inclusion criteria

- 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.

Exclusion criteria

- 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.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	29-07-2021
Enrollment:	129
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	25-01-2021
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 56152
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

Study results