Cisplatin pharmacokinetics and skeletal muscle mass in patients with head and neck cancer: is cisplatin overdosed in patients with low skeletal muscle mass?

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23217

Source
Nationaal Trial Register

Brief title
PLATISMA

Health condition

Toxicity, chemotherapy, body composition, head and neck cancer

Sponsors and support

Primary sponsor: University Medical Center Utrecht
Source(s) of monetary or material Support: Dutch Cancer Society (KWF)

Intervention

Outcome measures

Primary outcome

Relationship between cisplatin pharmacokinetics, skeletal muscle mass and body surface

area

Secondary outcome

- Chemotherapy related toxicity and dose-limiting toxicity

- Quality of life

- Hospital expenditures

Study description

Background summary

Treatment of advanced stage head and neck squamous cell carcinoma (HNSCC) by chemoradiotherapy (CRT) with platinum-based chemotherapy is associated with frequent severe toxicity, requiring treatment de-escalation or termination of chemotherapy in at least 30% of patients. In recent years a relationship between low skeletal muscle mass, as measured using routine diagnostic CT scans, and chemotherapy related toxicity has been suggested in a variety of tumour types including HNSCC. A potential explanation for this relationship is that platinum compounds such as cisplatin are hydrophilic and only distribute into the fat-free body mass. Skeletal muscle mass is the largest contributor to fat-free mass. Chemotherapy dose is currently calculated using a patient’s body surface area (BSA), which does not take into account abnormal body composition. The hypothesis of this study is that cisplatin pharmakinetic parameters have a stronger association with skeletal muscle mass than with BSA. It is possible that the current chemotherapy dosing method using BSA insufficiently takes into account individual differences in body composition, and that cisplatin is relatively overdosed in patients with low skeletal muscle mass. This study will investigate the association between cisplatin pharmacokinetics and skeletal muscle mass, and the correlation between cisplatin pharmacokinetics and BSA. Secondary, this study will investigate the association between cisplatin pharmacokinetics and chemotherapy related toxicity including dose-limiting toxicity and quality of life.

Study objective

In recent years a relationship between low skeletal muscle mass, as measured using routine diagnostic CT scans, and chemotherapy related toxicity has been suggested in a variety of tumour types including head and neck squamous cell carcinoma (HNSCC). A potential explanation for this relationship is that platinum compounds such as cisplatin are hydrophilic and only distribute into the fat-free body mass. Skeletal muscle mass is the largest contributor to fat-free mass. Chemotherapy dose is currently calculated using a patient’s body surface area (BSA), which does not take into account abnormal body composition. The hypothesis of this study is that cisplatin pharmakinetic parameters have a stronger association with skeletal muscle mass than with BSA. It is possible that the current

chemotherapy dosing method using BSA insufficiently takes into account individual differences in body composition, and that cisplatin is relatively overdosed in patients with low skeletal muscle mass.

Study design

- Baseline measurements of skeletal muscle mass, quality of life and other study related parameters before start of chemoradiotherapy

- One quality of life measurement during chemoradiotherapy

- One quality of life measurement after the end of chemoradiotherapy

Intervention

none

Contacts

Public

Scientific

Eligibility criteria

Inclusion criteria

• Diagnosed with HNSCC (histologically or cytology proven).

• Scheduled for CRT with conventional high-dose cisplatin with curative intent.

• Eighteen years of age or older, and able to exercise their free will.

• Sufficient understanding of the Dutch language to give informed consent.

Exclusion criteria

• Major CT artefacts, impeding accurate muscle tissue identification on CT imaging.

• Synchronous tumour(s) outside of the head and neck region, e.g. concurrent non-small cell lung cancer, for which the patienty receives concurrent treatment

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-07-2018
Enrollment:	50
Type:	Anticipated

Ethics review

Positive opinion

Date:	08-01-2019
Application type:	First submission

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
NTR-new	NL7469
NTR-old	NTR7711
Other	KWF subsidie: project number 11444 : METC UMC Utrecht protocolnummer 18-225/D

Study results