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

Gepubliceerd: 08-01-2019 Laatst bijgewerkt: 18-08-2022

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON23217

Bron
Nationaal Trial Register

Verkorte titel
PLATISMA

Aandoening

Toxicity, chemotherapy, body composition, head and neck cancer

Ondersteuning

Primaire sponsor: University Medical Center Utrecht
Overige ondersteuning: Dutch Cancer Society (KWF)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Relationship between cisplatin pharmacokinetics, skeletal muscle mass and body surface area

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

- 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

Onderzoeksproduct en/of interventie

none

Contactpersonen

Publiek

Wetenschappelijk

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• 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.

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

• 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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-07-2018
Aantal proefpersonen:	50
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	08-01-2019
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	NL7469
NTR-old	NTR7711
Ander register	KWF subsidie: project number 11444 : METC UMC Utrecht protocolnummer 18-225/D

Resultaten