Proton Image-guided Radiation Assignment for Therapeutic Escalation via Selection of locally advanced head and neck cancer patients [PIRATES]: A Phase I safety and feasibility trial

Gepubliceerd: 15-07-2021 Laatst bijgewerkt: 18-08-2022

The hypotheses is that image guided hybrid hyper-fractionated dose escalation with mucosal sparing proton therapy is a feasible and safe treatment for Locally Advanced Head and Neck Cancer patients.

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

Samenvatting

ID

NL-OMON24790

Bron
NTR

Verkorte titel
PIRATES

Aandoening

Locally Advanced Head and Neck Cancer (HPV-negative)

Ondersteuning

Primaire sponsor: MD Anderson Cancer Center; NWO
Overige ondersteuning: Dr. van Dijk, received/receives funding and salary support for initiation and execution of this trial from the Dutch organization NWO ZonMw via the Rubicon Individual career development grant.
Dr. Mohamed and Fuller received/receives funding and salary support unrelated to this project during the period of study execution from: the NIH National Cancer Institute (NCI)

Early Phase Clinical Trials in Imaging and Image-Guided Interventions Program (R01CA218148), the National Institutes of Health (NIH) National Institute for Dental and Craniofacial Research (NIDCR) Establishing Outcome Measures Award (R01DE025248/R56DE025248).
Dr. Fuller received funding unrelated to this project during the period of study execution from NIH/NCI Cancer Center (P30CA016672, P50 CA097007, and R01CA2148250); from NIH/NIBIB (R25EB025787-01); from NIH/NSF (NSF1557679); NSF-CMMI grant (NSF1933369); and the Sabin Family Foundation.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Severe unacceptable local adverse events which are radiotherapeutically attributable. Specifically, CTCAEv5 grade 4 mucositis, dermatitis or aspiration that does not resolve to a grade ≤3 in 3 months, and CTCAEv5 grade≤3 myelopathy, and/or osteonecrosis.

Toelichting onderzoek

Achtergrond van het onderzoek

This phase I trial studies the toxicities of dose-escalation with image-guided hybrid hyper-fractioned proton therapy in treating patients with (unresectable) locally advanced head and neck cancer. The in dose radiation frequency and additional boosr dose investigated in this study may help to better control the tumor and prevent it from coming back or growing. The goal of this study is to test a new radiation schedule that administers more radiation to the tumor tissue using image guided proton therapy for patients that have a high risk of having a tumor recurrence (the tumor comes back after treatment).

Doel van het onderzoek

The hypotheses is that image guided hybrid hyper-fractionated dose escalation with mucosal sparing proton therapy is a feasible and safe treatment for Locally Advanced Head and Neck Cancer patients.

Onderzoeksopzet

weekly during radiation, and at 6 weeks, 3, 6, 9, 12 months after therapy in the first year, subsequently every 4 months in the second year and then every 9 months

Onderzoeksproduct en/of interventie

Radiation dose escalation with image-guided hybrid hyper-fractionated with proton therapy, while sparing the mucosal and bone structures

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Biopsy proven diagnosis of squamous cell carcinoma of HNC originating in the oropharynx, hypopharynx, larynx, or oral cavity (base of tongue)
• The primary radiotherapy with curative intend, either in combination with chemotherapy or not
• Inoperable locally advanced disease, defined as:
• AJCC 8th stage ≥ III
• T stage ≥2
• Negative for HPV by p16 IHC or ISH

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Previous radiation treatment in the head and neck region
• Head and neck surgery of the primary tumor or lymph nodes except for incisional or excisional biopsies

• Pregnant or breast-feeding females
• Patients younger than 18 years
• Patients with ECOG performance score of 2 or lower
• Contraindications to MRI
• Patients that continue to smoke or abuse alcohol during treatment

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
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:	01-05-2021
Aantal proefpersonen:	18
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Toelichting

IPD will be shared after trial completion as allowed by national privacy requirements through a planned Data Descriptor publication of anonymized/deidentified data.

Ethische beoordeling

Positief advies

Datum:	15-07-2021
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	NL9603
Ander register	IRB MD Anderson Cancer Center : IRB 2019-0467

Resultaten