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

No registrations found.

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

Summary

ID

NL-OMON24790

Source
NTR

Brief title
PIRATES

Health condition

Locally Advanced Head and Neck Cancer (HPV-negative)

Sponsors and support

Primary sponsor: MD Anderson Cancer Center; NWO
Source(s) of monetary or material Support: 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.

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

Rates of grade 3 toxicity in 3 to 6 months after radiation oncology. Specifically, CTCAEv5 grade 3 mucositis, dermatitis, aspiration, dysphagia, hearing impaired, xerostomia, weight loss, trismus, hoarseness, oropharyngeal pain.

Study description

Background summary

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).

Study objective

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.

Study design

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

Intervention

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

Contacts

Public
MD Andeson Cancer Center
Lisanne van Dijk

+31655257381
Scientific
MD Andeson Cancer Center
Lisanne van Dijk

+31655257381

Eligibility criteria

Inclusion criteria

• 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

Exclusion criteria

• 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

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-05-2021
Enrollment:	18
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Plan description

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

Ethics review

Positive opinion

Date:	15-07-2021
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	NL9603
Other	IRB MD Anderson Cancer Center : IRB 2019-0467

Study results