Adaptive Dose-Escalated Multi-modality Image-guided RadiothErapy (ADMIRE) for head and neck cancer by twice re-imaging, re-delineation and re-planning during the course of radiotherapy

Published: 30-06-2017
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Primary objective: To investigate the feasibility of the adaptive radiotherapy scheme.Secundary objectives:To examine the toxicity of the adaptive RT schemeTo investigate the locoregional tumor controlTo examine the prognostic value of the different...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Miscellaneous and site unspecified neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON47484

Source
ToetsingOnline

Brief title
ADMIRE

Condition

- Miscellaneous and site unspecified neoplasms malignant and unspecified

Synonym
Head and neck cancer

Research involving
Human

Sponsors and support

Primary sponsor: Antoni van Leeuwenhoek Ziekenhuis
Source(s) of monetary or material Support: TKI project van afdeling radiotherapie

Intervention

Keyword: Adaptive, Head and neck cancer, Image-guided, Radiotherapy

Outcome measures

Primary outcome

The feasibility of the adaptive radiotherapy schedule will be rejected in case

of:

- Occurrence of intolerable radiation-induced acute toxicities.

- The inability to implement 80% of the adaptive treatment plans within 2 days

from the intended starting day (day 13 and day 23 of treatment).

Secondary outcome

To examine the toxicity of the adaptive radiotherapy scheme according to the

CTCAE v4.0 scoring system

The locoregional tumor control

The mean value of the different imaging modalities within the tumor will be

measured at baseline and during week 2 and 4. Using these, the relative

response will be calculated for the following modalities:

- FDG-PET: decrease of the SUV-value

Study description

Background summary

Although tremendous gains have been achieved over the last few decades in

patients with head and neck cancer (HNC) treated by means of (chemo)radiation with regard to loco-regional control (LRC) and overall survival (OS), the balance between tumor control and toxicity is still very delicate. The cure rates remain inadequate in certain subgroups of patients, while treatment toxicities and deterioration of quality of life (QoL) are considerable.
Most recurrences appear within the FDG-avid area and radioresistance is heterogeneous within the tumor. A biologically adaptive radiotherapy approach, where the treatment plan is re-optimized during treatment based on repeat functional imaging, can increase the dose to the less responding (radioresistant) parts of the tumor while decreasing the dose to the good responding parts of the tumor. Thereby improving the therapeutic ratio (increasing cure rates while maintaining or decreasing treatment-related side effects).
This trial aims to investigate the feasibility of an adaptive radiation approach using multi-modality imaging and a PET-guided mild dose escalation to improve oncologic outcomes.

Study objective

Primary objective:
To investigate the feasibility of the adaptive radiotherapy scheme.

Secundary objectives:
To examine the toxicity of the adaptive RT scheme
To investigate the locoregional tumor control
To examine the prognostic value of the different imaging modalities

Study design

Feasability study of the adaptive radiotherapy scheme.

Intervention

Patients with primary head and neck squamous cell carcinoma (HNSCC) planned for treatment with radiotherapy with or without chemotherapy in curative setting will be treated with an adaptive radiotherapy scheme. An FDG-PET/CT scan for re-delineation and re-planning will be made at the end of the second and fourth of week of radiotherapy. The non-responding part of the tumor on FDG-PET will receive a mild dose-escalation. Depending on the metabolic response, the entire tumor will receive 70 Gy or the residual FDG-avid area will receive 74 or 78 Gy. If there is a complete metabolic response on the FDG-PET after 2 weeks, the entire tumor will receive 70 Gy. If there is a complete metabolic response after 4 weeks of treatment, the residual FDG-avid area will receive 74 Gy. If there also is no complete metabolic response after 4 weeks of treatment, the residual FDG-avid area will receive 78 Gy.

Study burden and risks

Patients included in the study will receive additional imaging with FDG-PET/CT and MRI as listed in the schedules below. These imaging procedures will be combined with treatment visits in week 2 and 4. FDG-PET/CT requires 6 hours fasting. The FDG-PET/CT scans come with an additional radiation burden: 2 x low dose FDG-PET (2 mSv) + low dose CT (2.5 mSv), for a total of 9 mSv. This is within the range of normal diagnostic procedures, and is not considered a significant risk in the selected population with cancer and an indication for external beam radiotherapy. The increased radiation dose is mild and directed only to the non-responding part of the gross tumor volume at FDG-PET. Therefore it is not expected to increase side-effects.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Histologic biopsy confirmed squamous cell carcinoma of the oral cavity, HPV-negative oropharynx, hypopharynx or larynx
T2-T4
Scheduled for radiotherapy or radiotherapy with cisplatin or cetuximab

Exclusion criteria

GFR<30
Other neoplasms with metastases in the previous 3 years

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-12-2017
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	30-06-2017
Application type:	First submission
Review commission:	METC NedMec

Approved WMO

Date:	27-10-2017
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	12-04-2018
Application type:	Amendment
Review commission:	METC NedMec

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
CCMO	NL60921.031.17

Study results