Functional Imaging during Radiation Therapy for HNC using FDG-PET, HX4-PET and MRI

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Primary objectives: To examine the ability of functional imaging signal changes over the course of treatment to distinguish patients with and without local recurrenceSecundary objectives:To examine the correlation between the different imaging...

Ethical review	Not approved
Status	Will not start
Health condition type	Miscellaneous and site unspecified neoplasms malignant and unspecified
Study type	Interventional

Summary

ID

NL-OMON42671

Source
ToetsingOnline

Brief title
FAITH

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: afdeling RT

Intervention

Keyword: Head and Neck cancer, imaging, radiotherapy

Outcome measures

Primary outcome

Determining the Ktrans, ADC, FDG-PET SUV en HX4-PET SUV signal changes during radiotherapy. Calculating the differentiating abilities between patients with and without a recurrence of these signal changes

Secondary outcome

Determine the correlation between the average signal changes during treatment of the different modalities.

Determine the signal heterogeneity within the treatment and the heterogeneity differences between patients.

Determine the prognostic value of the change in tumor volume.

Study description

Background summary

Although tremendous gains have been achieved over the last few decades with regard to loco-regional control (LRC) and overall survival (OS) in patients with head and neck cancer (HNC), the balance between tumor control and toxicity in patients with HNC treated by means of (chemo)radiation is still very delicate. The cure rates remain inadequate in patients with locally advanced tumors, especially HPV negative tumors. Moreover, the toxicity of treatment and deterioration of quality of life (QoL) are considerable.
Physiological properties of the tumor like hypoxia and cell proliferation influence the treatment resistance of the tumor. Multiple functional imaging modalities can describe these physiological properties and have shown their usage in predicting treatment outcome during radiotherapy. However, the optimal combination of these modalities and their interplay is not clear. We will examine which imaging modality or which combination of imaging modalities has the best prognostic value, and which one can identify the subvolumes of the

tumor with the strongest association with loco-regional failure.

Study objective

Primary objectives:
To examine the ability of functional imaging signal changes over the course of treatment to distinguish patients with and without local recurrence

Secundary objectives:
To examine the correlation between the different imaging modalities and the change in this correlation during treatment
To examine the heterogeneity and spatial distribution within the tumor of the functional imaging signals and the correlation between the modalities
To examine the prognostic value of change in tumor volume during treatment

Study design

Patients will have additional imaging before, during and after the treatment. Patients are treated with radiotherapy or chemoradiotherapy (possibly with accelerated fractionation). This treatment will not be altered by the study design. The week before the treatment patients will receive an additional MRI, FDG-PET and HX4-PET. These examinations will be repeated during week 2 and 4 of the treatment. Twelve weeks after the treatment patients will receive a FDG-PET and MRI. During the standard investigation under general anaesthesia, additional biopsies will be taken and markers will be placed at the biopsy location. Before the start of the treatment and 4 and 12 weeks after treatment, additional blood samples will be taken.
When there is clinical or radiological suspicion of a recurrence, an additional MRI and FDG-PET in treatment mask will be made.

Intervention

additional diagnostic scans
- 4 x FDG-PET/CT
- 4 x MRI
- 3 x HX4-PET/CT

Study burden and risks

Patients included in the study will receive additional imaging with PET/CT and MRI as listed in the schedule below (table 1 a and 1 b). These imaging procedures require additional visits to the hospital in the week before treatment (combined with other appointments where possible), and will be combined with treatment visits in week 2 and 4. FDG-PET/CT requires 6 hours fasting. The PET/CT scans come with an additional radiation burden: 4 x low dose FDG-PET (4 x 2 mSv) + 4 x normal dose CT (4 x 2.5 mSv) + 3 x low dose CT

(3 x 1.25 mSv) and 3 x HX4-PET (3 x 12 mSv), for a total of 57.75 mSv. Additionally, there will be one extra FDG-PET/CT when a recurrence is suspected (1x low dose FDG-PET (2 mSv) + 1x normal dose CT (2.5 mSv), expected in 1/5 patients, total of 62.25 mSv). This is not considered a significant risk in the selected population with cancer and treatment with external beam radiotherapy. All patients will receive 3 additional MRI*s (1 before and 2 during treatment). Twelve weeks after treatment and in case of a suspected recurrence, either a diagnostic CT or MRI will be made. When a CT instead of a MRI is indicated (tumor below the hyoid), an additional study MRI will be made. The total additional MRI*s will vary between 3 and 5. 5 additional MRI exams, An intravenous contrast agent will be injected (15 ml Gadoteric acid) during the MRI. No adverse effects of this agent have been registered. However, an allergic reaction can in principle not be excluded. For patients who already received a similar MRI exam as a part of their treatment, the risk associated with the repetition of the MRI will be very limited. The FDG-PET scans will take 1 hour post injection time and 20 minutes scantime, the HX4-PET scans will take 4 hours post injection time and 30 minutes scantime, the MRI*s 30 minutes scantime. The additional blood and tissue collection will cause minimal risks. An extra venipuncture will cause a very small and well treatable risk of hematoma or infection. The additional biopsies will bring a small change of infection or bleeding.

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 SCC oral cavity, oropharynx, hypopharynx, and larynx
- HPV negative tumors
- Largest tumor diameter at least 3 cm (primary tumor)
- Scheduled for concurrent chemoradiotherapy or definitive external beam radiotherapy (DAHANCA schedule and normal fractionation are both applicable)

Exclusion criteria

- SCC of the nasopharynx, nasal cavity, paranasal sinuses, salivary gland and thyroid gland
- Expected failure from follow-up
- Patients who are not expected to participate in at least 2 out of 3 imaging modalities (MRI, HX4-PET and FDG-PET)
- Pregnancy or lactation
- Patients (M/F) with reproductive potential not implementing adequate contraceptives measures at least 14 days before the first study procedure
- Prior surgery, radiotherapy or chemotherapy for this tumor
- Previous malignancies within the last 2 years except for adequately treated basal cell carcinoma of the skin and carcinoma in situ of the cervix

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	56
Type:	Anticipated

Ethics review

Not approved

Date:	31-03-2016
Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

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	NL55413.031.15