Prospective monitoring of osteoradionecrosis after postoperative radiotherapy for oral cavity cancer.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON29332

Source
NTR

Brief title
POPROC

Health condition

Oral cavity cancer, Osteoradionecrosis

Sponsors and support

Primary sponsor: Erasmus MC
Source(s) of monetary or material Support: Erasmus MC, Da Vinci Kliniek

Intervention

Outcome measures

Primary outcome

The incidence of osteoradionecrosis and the development of associated complaints over time including early signs of osteoradionecrosis after postoperative radiotherapy for oral cavity cancer

Secondary outcome

- Changes in quality of life and oral functioning (as measured in EORTC QLQ C30, H&N 35, Eq5D, and EAT-10)
- the development of trismus, graded over time according to CTCAE 5.0 and mouth opening
- the development of xerostomia, graded over time according to CTCAE 5.0 and measurements in H&N35
- the development of dysphagia, graded over time according to CTCAE 5.0 and measurements in H&N 35 & EAT-10
- the development of self-reported main symptoms of ORN (as measured in MYMOP) over time.

Study description

Background summary

Rationale: Osteoradionecrosis (ORN) is a severe late toxicity that can occur after radiotherapy. In severe cases, ORN can lead to extensive bone necrosis, spontaneous fractures of the jaw and fistulas, requiring repeated hospital visitation, and in some cases surgical reconstruction. Patients who undergo postoperative radiotherapy (PORT) for oral cavity cancers are at higher risk for developing ORN. A prospective cohort study can help us better understand the development over time and early signs of ORN, as well as predictive and prognostic factors.

Primary objective: To investigate in a prospective setting the incidence of osteoradionecrosis and the development of associated complaints over time including early signs, after PORT for oral cavity cancer.

Study population: Patients (n=120) with oral cavity cancer T1-4 N0-3 M0 referred for postoperative (chemo)radiotherapy at the Erasmus MC as a primary treatment with curative intent after surgery (local excision or extensive).

Intervention: All interventions are according to applicable standard clinical procedures & protocols for oral cavity cancer treatment at the Erasmus MC Cancer Center.

Main study endpoints: osteoradionecrosis (defined as the presence of exposed bone in irradiated tissue without the presence of tumor recurrence), graded over time according to Notani and CTCAE and RTOG/EORTC criteria.

Study objective

We hypothesize that the incidence of osteoradionecrosis is higher in patients who undergo postoperative radiotherapy for oral cavity cancers, than in other patients who undergo radiotherapy of the head and neck, and that there are clear early signs of osteoradionecrosis

that can be helpfull in early detection of osteoradionecrosis.

Study design

Measurements and clinical data will be collected during regular clinical appointments and follow up visits. PROMS will be send previous to clinical meeting.

Contacts

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Eligibility criteria

Inclusion criteria

- Receiving postoperative external beam radiotherapy with curative intent at the Dept of Radiotherapy at Erasmus MC (including treatment after a locoregional recurrence and/or chemoradiotherapy).
- Written informed consent.
- Patient 18 years or older.

Exclusion criteria

- Patients with RT of the neck region III-V only (for instance after lymph node recurrence)
- Patients who are treated simultaneously for other tumors outside the oral cavity.
- Patients who previously were treated with radiotherapy in the head & neck region.
- Patients with a Karnofsky Performance Status <70
- Patients with limited fluency in Dutch (inadequate to comprehend the questionnaires).

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-10-2021
Enrollment:	120
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	13-09-2021
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	NL9728
Other	METC Erasmus MC : MEC-2021-0453

Study results