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

Gepubliceerd: 13-09-2021 Laatst bijgewerkt: 18-08-2022

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...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON29332

Bron
NTR

Verkorte titel
POPROC

Aandoening

Oral cavity cancer, Osteoradionecrosis

Ondersteuning

Primaire sponsor: Erasmus MC
Overige ondersteuning: Erasmus MC, Da Vinci Kliniek

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Contactpersonen

Publiek

Erasmus MC
Michelle Möring

010 704 0704

Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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).

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	15-10-2021
Aantal proefpersonen:	120
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	13-09-2021
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	NL9728
Ander register	METC Erasmus MC : MEC-2021-0453

Resultaten