Guided by light: Optimizing surgical excision of oral cancer using real-time fluorescence imaging

Gepubliceerd: 27-09-2019 Laatst bijgewerkt: 18-08-2022

This clinical trial will determine the optimal dose of cRGD-ZW800-1 and investigate the feasibility of intraoperative FLI to adequately assess tumor margins in patients with oral cancer.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24301

Bron
NTR

Verkorte titel
FLU-OR-IN

Aandoening

Squamous Cell Carcinoma of the Oral Cavity

Ondersteuning

Primaire sponsor: Erasmus University Medical Center
Overige ondersteuning: KWF Kanker Bestrijding

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Mean tumor-to-background ratio (TBR)
2. Rate of adequate (i.e. >5mm clear) tumor resection margins

Toelichting onderzoek

Achtergrond van het onderzoek

Head and neck cancer (HNC) is the 9th most common tumor worldwide, a third of them arising in the oral cavity. Complete tumor resection of oral cancer is the most important surrogate marker for survival. Precise margin delineation is imperative in the delicate head and neck region where wider resections inevitably lead to increased morbidity and loss of functionality.
In current practice, intraoperative assessment of the tumor-free margin is dependent on visual appearance and palpation of the tumor. We have reported inadequate surgical margins in up to 85% of patients with oral cancer, which is unacceptable. Therefore, new intraoperative visualization techniques are required to assess tumor margins in real-time and to guide surgical removal of oral cancer with adequate tumor-free margins while retaining maximal functionality.
Fluorescence imaging (FLI) using near-infrared light has recently emerged as a revolutionary technique to provide real-time visualization of tumor tissue, enabling image-guided surgery. Tumor-specific fluorescent targeting agents are systemically injected preoperatively and real-time FLI is performed using a dedicated intraoperative camera system. In this study, we will test the use of cRGD-ZW800-1, a tumor-specific agent that targets integrins, for intraoperative detection and margin delineation of oral cancer. Overexpression of a wide range of integrin receptors is reported in HNC.
The overarching goal of this two-staged clinical trial is to improve adequate resection of oral cancer.

Doel van het onderzoek

This clinical trial will determine the optimal dose of cRGD-ZW800-1 and investigate the feasibility of intraoperative FLI to adequately assess tumor margins in patients with oral cancer.

Onderzoeksopzet

-

Onderzoeksproduct en/of interventie

cRGD-ZW800-1 injection prior to surgery

Contactpersonen

Publiek

Erasmus University Medical Center
Stijn Keereweer

010 7041357

Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1) Patients with biopsy-proven squamous cell carcinoma of the oral cavity, eligible for surgical resection of the primary tumor;
2) ≥ 18 years of age;
3) Before patient registration, written informed consent must be given according to ICH/GCP, and national/local regulations.
4) Screening ECG and clinical laboratory test results are within normal limits, or if any are outside of normal limits, they are considered to be clinically insignificant;
5) The patient has a normal or clinically acceptable medical history, physical examination, and vital signs findings at screening;
6) Absence of any psychological, familial, sociological or geographical condition potentially hampering compliance with the study protocol and follow-up schedule; those conditions should be discussed with the patient before registration in the trial.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1) Previous surgery, chemotherapy or radiotherapy to the oral cavity;
2) History of a clinically significant allergy or anaphylactic reactions to any of the components of the agent.

3) Patients pregnant or breastfeeding, lack of effective contraception in male or female patients with reproductive potential;
4) Any condition that the investigator considers to be potentially jeopardizing the patients well-being or the study objectives.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2020
Aantal proefpersonen:	29
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL8049
Ander register	METC EMC : 12175

Resultaten