Diagnostics using perfusion CT imaging to determine the extent of bone marrow involvement of the mandible by squamous cell carcinoma - a pilot study

Published: 20-04-2010
Last updated: 06-05-2024

To demonstrate the extent of bone marrow invasion of the mandible by SCC. Can perfusion CT imaging demonstrate the extent of bone marrow invasion of the mandible by SCC? If so, it can prevent unnecessary resection of the mandible.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Soft tissue neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON35141

Source
ToetsingOnline

Brief title
Bone marrow involvement of the mandible using perfusion CT imaging

Condition

- Soft tissue neoplasms malignant and unspecified

Synonym
oral cancer, oral cavity carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: mandible, perfusion CT imaging, squamous cell carcinoma

Outcome measures

Primary outcome

Determine the extension of bone marrow involvement of the mandible by SCC.

Secondary outcome

Perfusion CT imaging can prevent unnecessary resection of the mandible.

Study description

Background summary

Squamous cell carcinoma (SCC) is the most common malignant oral cavity tumor with approximately 800 new cases every year in the Netherlands. Treatment of SCC adjacent or fixed to the mandible is (wide) surgical excision resection in continuity with the affected bone. Continuity of the mandible may be maintained (marginal resection) or disrupted (segmental resection). Marginal resection is in general sufficient, if there is no or only limited bone marrow involvement. Loss of mandibular continuity may cause functional, aesthetic and social problems when the mandible is not reconstructed. Immediate reconstruction of the mandible, most often with a free vascularized bone flap, is the treatment of choice. These operations are time consuming, require a two-team approach and demand a long postoperative hospital stay. Postoperative histopathologic findings show that high percentages of the resected mandibles (35-78%) do not demonstrate signs of bone marrow involvement. This emphasizes the lack of reliable screening imaging techniques. There are several imaging techniques that have the ability to visualise tumor ingrowth in the mandible. Up till now often a combination of imaging techniques is used to accurately predict bone invasion. It nevertheless remains difficult to demonstrate the extent of bone marrow invasion in the mandible. Perfusion CT imaging can possibly demonstrate the extension of bone marrow invasion in the mandible by squamous cell carcinoma. Perfusion CT imaging has been used in the past to differentiate benign from malignant head and neck lesions, to predict and measure the effect of chemotherapy and to quantify neoplastic microcirculation.

Study objective

To demonstrate the extent of bone marrow invasion of the mandible by SCC. Can perfusion CT imaging demonstrate the extent of bone marrow invasion of the mandible by SCC? If so, it can prevent unnecessary resection of the mandible.

Study design

An observational study.

Study burden and risks

The burden for participants in this study is negligible. Extra CT images are made prior to the conventional head and neck CT, but in the same session. This will take place during a hospital stay as part of the preoperative screening. The risks associated with participation are possibly the extra bolus of contrast agent and the longer scanning procedure. This means a higher radiation dose. The higher radiation dose, however, is negligible in comparison with the radiation dose of the postoperative radiation therapy, which is indicated in almost all patients with bone marrow involvement.

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

Patients, 18 year of age or older, with a squamous cell carcinoma of the oral cavity or oropharynx, fixed to the mandible. Conventional X-ray imaging shows cortical or bonemarrow mandibular involvement.

Exclusion criteria

Prior surgry in the head and neck region or cervicofacial radiotherapy. Mandibular osteomyelitis, recent tooth removal(s). Allergy for contrast agent. Severe kidney diseases.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-08-2010
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	20-04-2010
Application type:	First submission
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	NL26236.041.09