Effects of radiation therapy on oral mucosa microcirculation in patients with malignant disease in the head and neck region.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON39703

Source
ToetsingOnline

Brief title
Response of oral microcirculation to irradiation.

Condition

- Other condition
- Soft tissue neoplasms malignant and unspecified
- Vascular injuries

Synonym
inflammation of oral mucous membrane., oral mucositis

Health condition

bloeddoorstroming in de microvaten

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: head and neck region, microcirculation, oral mucosa, radiotherapy

Outcome measures

Primary outcome

- capillary enumeration (i.e. counting of the capillary loops present in each

visual field). From 5 captured video frames an average will be computed and

recorded to represent the capillary density.

- a close observation will be made of the morphology of the capillaries.

Because we do not know what to expect here, this will be noted discriptively

afterwards.

Secondary outcome

-

Study description

Background summary

When radiotherapy (RT) is applied as a treatment in head and neck cancer patients, it is inevitable that damage ensues in the tissues surrounding the tumor, which results in oral complications that include among others oral mucositis (OM), xerostomia, mucosal and bone necrosis. These pathological conditions are classified as acute, consequential and/or late side effects. The acute injury, which consists of mucositis, arises in 80% of the patients during the course of curative radiation. Mucositis is mainly caused by the effect of radiotherapy on the rapidly proliferating cells of the mucosa, shown as atrophy

of the squamous epithelial cells and inflammatory infiltration. Hence no vascular damage is present at this time except for an increase in permeability due to the inflammation.

As a late adverse effect, RT injures the microvasculature in the vasculoconnective tissue (slow turnover of cells). Early damage of the vasculature by the inflammatory response with the release of vasoactive cytokines (acute fase) causes fibrin to leak into the tissues, which promotes collagen deposition. Vascular lumen can get blocked which may lead to reduced tissue vascularity and regional hypoxia as a late effect of radiotherapy. Hypocellularity and decreased metabolism may eventually induce ulceration, and/or atrophy of the epithelium. However, late effects and ulceration usually does not occur until doses respectively of 50.0 and 65.0 Gy (conventional fractionation) are used.
Late effects can also arise several years after RT. Tissue invasion, by for example trauma or surgery, can drive the propensity for wounds to follow a course of tissue breakdown by impaired healing, wound dehiscence, infection, and altered repair and regeneration.

Although the effects of RT on the microcirculation have been investigated previously in other tissues using invasive techniques based on histological methods and intravital capillaryscopy, it has never before been evaluated using SDF imaging. SDF technology is built into a practical handheld instrument providing great ease in mobility with noninvasive data acquisition of images with high resolution and contrast between microvessels and the surrounding parenchyma. The compact and noninvasive nature of the technique enables the investigator to easily apply the instrument to mucosal tissue surfaces, such as in the oral cavity, and navigate to areas that would otherwise be too challenging for other imaging techniques to reach.

Study objective

The aim of this study is to elucidate the effects of RT on the oral microcirculation in patients with malignant disease in the head and neck region. We want to test the hypothesis that radiation therapy triggers microcirculatory derangements which ultimately lead to late effects as ulceration and osteoradionecrosis (ORN) in cancer patients. The question we aim to address is the following: what are the effects of radiation therapy on the microvasculature of the oral mucosa in the acute and late phase regarding capillary density and morphology of the microcirculation.

Study design

This is a single center prospective, longitudinal, observational clinical investigation on the effects of radiation therapy on the oral mucosal microcirculation in patients with oropharyngeal malignancies.

Study burden and risks

Burden: Besides the treatment the patient wil undergo for his malignancy, our study will only add up the SDF imaging technique to the patients burden. As mentioned earlier SDF is a non-invasive technique which only requires contact with the tissue. This might give the patient a unpleasant feeling. This action will aproximately take 10 min of extra time. This measurement will be repeated 9 times during the study.

Risks: There will be no additional risks for the patient as SDF is an non-invasive technique.

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 receiving radiotherapy with curative intent in the Department of Radiotherapy in The
Netherlands Cancer Institute/Antoni van Leeuwenhoek Hospital in Amsterdam
* Histology proven squamous cell carcinoma of the oropharynx and oral cavity.
* Informed consent from each participating patient.
* Patients older than 18 years.

Exclusion criteria

* Patients receiving other cancer treatment besides radiotherapy: systemically (e.g. chemotherapy) or in the area that will be measured (e.g. surgery).
* Patients with insulin-dependent diabetes.
* Patients that did not sign informed consent
* Patients younger than 18 years

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-06-2013
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	01-11-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-07-2014
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL37890.018.12