

Effects of hyperbaric oxygen therapy on resuscitating mucosal microcirculation and tissue repair in patients who received radiotherapy for malignant disease in the head and neck region

Published: 01-07-2014

Last updated: 21-04-2024

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

Summary

ID

NL-OMON45130

Source

ToetsingOnline

Brief title

Response of microcirculation to hyperbaric oxygen therapy.

Condition

- Other condition
- Head and neck therapeutic procedures
- Vascular injuries

Synonym

atrophy of the epithelium, decreased vascularity, obliterative endarteritis

Health condition

bloedoorstroming in de microvaten

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Nuts-Ohra

Intervention

Keyword: head and neck region, hyperbaric oxygen therapy, microcirculation, oral mucosa

Outcome measures

Primary outcome

- Capillary enumeration (i.e. counting of the capillary loops present in each visual field). The average from 5 captured video frames will be computed and recorded to represent the capillary density at each time point in all patients.
- We will make a close observation of the morphology. Given that we do not know what to expect, this will not be quantified other than noted descriptively afterwards.

Secondary outcome

-

Study description

Background summary

Common complications associated with head and neck irradiation are mucositis (acute phase), xerostomia, and necrosis of both the mucosa and the underlying jaw bones. A late side effect of radiotherapy is damage of tissue microcirculation as a result of obliterative endarteritis, this causes decreased vascularity and consequently induces regional hypoxia. These late side effects may occur years after radiation. Tissue invasion, later in life,

by trauma or surgery could result in wound dehiscence, infection, and altered healing and regeneration.

Patients that received radiation therapy for malignancies in head and neck often are treated with hyperbaric oxygen therapy (HBOT) before a tooth gets extracted, implants are placed or any other form of oral surgery is performed. It is thought that through improving oxygenation of the tissue by HBOT, the risk of developing osteoradionecrosis (ORN) is reduced and the potential for healing is sustained. However, until this day clear evidence behind the efficacy and the exact working mechanism of HBOT is still lacking. Wound healing responses to HBOT, quantified by parameters such as perfusion and blood flow, were studied using different techniques and yielded often inconsistent results. Currently, patients with oral tissue complications are treated with sessions of HBOT without following a standardized protocol that specifies the amount of treatment sessions necessary to achieve curative goals of the pathology in question; improvement of symptoms is used as a guideline for identifying the required HBOT sessions.

Osteoradionecrosis (ORN) currently appears to emerge less frequently after tooth extraction in irradiated patients compared to the past. Studies show that the incidence of ORN is 2% after 1990 compared to 16% prior to the 1990s, presumably due to improved surgical methods and refined approaches to head and neck irradiation. Despite these improvements, an important question is raised as to whether hyperbaric oxygen should be applied as a supportive therapy; it has so far yielded controversial scientific results, is not easily available, and remains an expensive service. Furthermore, preparations usually take a month and are a burden for the patient. We aim to elucidate the efficacy of HBOT and its clinical applicability in preventing ORN and improving wound healing in patients with ORN. This is important as not every patient benefits from hyperbaric oxygen, also it will be possible to estimate the degree of efficacy per patient in advance.

With the SDFI technique it is possible to visualize the oral microcirculation, its changes, and red blood cell flow dynamics with high resolution. The SDFI device is built as a compact practical handheld instrument. This gives advantages in navigating areas that would otherwise be too challenging for other imaging techniques to reach. To our knowledge there are no *real time* clinical studies showing direct effects of HBOT on parameters of tissue perfusion and microcirculation.

Study objective

With this study we aim to elucidate the effects of HBOT on the oral microcirculation in patients with malignant disease in the head and neck region after receiving radiotherapy (RT). We want to test the hypothesis that HBOT improves RT-induced microcirculatory derangements, which may ultimately prevent or improve effects as ulceration and osteoradionecrosis (ORN) in head and neck cancer patients. The question we aim to address is the following: what are the effects of HBOT on the microvasculature of the oral mucosa after enduring

irradiation in the past regarding capillary density and morphology of the microcirculation.

Study design

This is a prospective, single center, longitudinal, observational clinical investigation on the effects of hyperbaric oxygen therapy on the oral mucosal microcirculation in patients with oropharyngeal malignancies after receiving radiotherapy in the past.

Study burden and risks

The burden associated with participation will be minimal given that the SDF imaging technique is non-invasive and only requires contact with the oral tissue. This might be an unpleasant feeling in patients who have a painful mucosa. The measurement requires 10 minutes of the patients time and will be repeated 8 times. There will be no risks associated with participation.

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 referred to the Department of Hyperbaric Medicine in the AMC for treating osteoradionecrosis and nonhealing ulcerations associated with a previous history of RT in the head and neck region.
- Patients referred to the Department of Hyperbaric Medicine in the AMC for HBOT prior to and after surgical intervention in the irradiated oral tissue.
- Patients ≥ 18 years.
- Informed consent.

Exclusion criteria

- Patients with oral surgery within the last month prior to the start of the investigation.
- Trismus that complicates sufficient mouth opening for measurements.
- Mucosa that is too painful for measurements.
- Patients < 18 years.
- No signed informed consent.

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): 28-11-2014

Enrollment: 50

Type: Actual

Ethics review

Approved WMO
Date: 01-07-2014
Application type: First submission
Review commission: METC Amsterdam UMC
Not approved
Date: 24-08-2015
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	NL49017.018.14