Treatment of Cancer in the Head and Neck:
The Role of Hyperbaric Oxygen in Reducing Swallowing Problems

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Primary Study Objectives:This study tries to objectives the potential benefit of prophylactic HBOT in terms of reducing / limiting the amount of dysphagia and / or xerostomia for tumors in the head and neck, specifically originating from the...

Ethical review	Approved WMO
Status	Pending
Health condition type	Miscellaneous and site unspecified neoplasms benign
Study type	Interventional

Summary

ID

NL-OMON39489

Source
ToetsingOnline

Brief title
HBOT in Head & Neck Cancer

Condition

- Miscellaneous and site unspecified neoplasms benign

Synonym
Dysphagia/Swallowing

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

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

Intervention

Keyword: Dysphagia, Hyperbaric oxygen, Radiotherapy, Side-effect

Outcome measures

Primary outcome

Quality of Life of the patients (dysphagia, xerostomia)

Quality of Life

The assessment of QoL will be performed using disease-specific aspects, that is the Performance Status Scale for Head and Neck cancer (PSSHN) 22. The performance status scale includes the daily core activities: ability to eat in public, normalcy of speech, and normalcy of diet. The eating in public subscale assesses the impact of eating function disturbances on the social integration of the patient by reporting restrictions of settings and people present during food intake. The understandability of speech subscale rates the degree to which the interviewer is able to understand the patient*s speech. The normalcy of diet subscale assesses the food the patient is able to eat, with categories spanning the range form normal diet to no-oral feedings. The three subscales are rated from 0 to 100, with 100 representing normal function.
The EORTC QLQ-C30 and the EORTC QLQ-H&N35 and MDADI questionnaires will also be used during the protocol to assess the Quality of Life. Finally, the 4 items of the score card should be scored with every outpatient clinic visit.

Secondary outcome

Tumor Control

The actuarial Local-Regional Control (LRC) rate, Disease Free Survival (DFS),

and Overall Survival (OS) rates will be calculated. Kaplan Meijer Curves will

be generated.

Study description

Background summary

Positive pilot study in reducing side-effects after radiation treatment in head and neck cancer patients.

Study objective

Primary Study Objectives:

This study tries to objectives the potential benefit of prophylactic HBOT in terms of reducing / limiting the amount of dysphagia and / or xerostomia for tumors in the head and neck, specifically originating from the nasopharynx and oropharynx. Moreover, given that patients with tumors in the hypopharynx and the T3-4 tumors of the larynx also complain of dysphagia and xerostomia, frequently occurring late side effects, the HBO prophylactic treatment might also apply to these tumors.

Dysphagia

• Can HBO reduce the amount of RT-induced dysphagia in patients with cancer of the head and neck?

Xerostomia

• Can HBO reduce the amount of RT-induced xerostomia in cancer of the head and neck?

Trismus

• Can HBO reduce the amount of surgically and / or RT-induced trismus in cancer of the head and neck?

Grade 3/4 (WHO) Mucositis

• Can HBO reduce the amount of RT-induced mucositis in cancer of the head and neck?

Secondary Study Objectives:

• What is the localregional control / (overall) survival in patients with cancer of the head and neck (standard protocol) with or without HBO

Study design

Included patients will be randomized in receiving yes or no hyperbaric oxygen treatment.

Intervention

Hyperbaric oxygen treatment.

Study burden and risks

Patients will receiving an additional treatment of hyperbaric oxygen sessiosn of 30 x 2 hours a day.

Contacts

Public
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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 with histological proof of squamous cell carcinoma of mucous membranes of the oropharynx, oral cavity, nasopharynx, hypophayrnx and larynx to be treated with curative intent
• Karnofsky score of 70 or higher
• Age >= 18 years
• Written informed consent given prior to start of the treatment protocol

Exclusion criteria

Pregnant woman
Heart injection fraction of < 30%
COPD or lungemphysema
Infection in the upper airways
Recent middle ear surgery
Recent thorax surgery
Uncontrolled fever
Severe epilepsia
Carefullness with claustrofobic patients
Carefullnes in patients with a medical history pneumothorax, thorax surgery or epileptic insults,

Study design

Design

Study type:	Interventional
Intervention model:	Parallel

Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2012
Enrollment:	80
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Conoxia
Generic name:	Oxygen
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	29-06-2012
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO Date:	15-11-2012
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
Other	25123615
EudraCT	EUCTR2012-001416-27-NL
CCMO	NL39443.078.12