Xerostomia after submandibular gland sparing radiotherapy

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The objective of this study is to determine the prevalence of xerostomia after radiotherapy of oropharyngeal tumors when sparing the parotid glands and one submandibular gland.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Miscellaneous and site unspecified neoplasms benign
Study type	Observational non invasive

Summary

ID

NL-OMON31993

Source
ToetsingOnline

Brief title
Xerostomia after radiotherapy

Condition

- Miscellaneous and site unspecified neoplasms benign

Synonym
oropharyngeal cancer

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: KWF Kankerbestrijding

Intervention

Keyword: Parotid gland, Radiotherapy, Submandibular gland, Xerostomia

Outcome measures

Primary outcome

The number of patients with patient-reported xerostomia one year after

radiotherapy determined using questionnaires (EORTC QLQ-H&N 35).

Secondary outcome

Objectively determined submandibulair flow complication. A complication is

defined as a submandibular flow less than 25% of the pre-radiotherapy values.

General quality of life after submandibular gland sparing radiotherapy.

Radiation-induced damage to the salivary system detected by MRI.

Study description

Background summary

Xerostomia after radiotherapy of the head-and-neck is a severe complication caused by radiation damage to the salivary system. In a previous study we have determined the prevalence of xerostomia after parotid gland sparing radiotherapy. Although the function of the parotid glands was partly preserved, still a large number of patients complained of moderate to severe xerostomia. This probably due to radiation damage to the submandibular gland which produces saliva during rest. In this study we now spare, besides the parotid glands, also one submandibular gland. The prevalence of xerostomia in this group will be compared with that in the previous group.

Study objective

The objective of this study is to determine the prevalence of xerostomia after radiotherapy of oropharyngeal tumors when sparing the parotid glands and one submandibular gland.

Study design

Patients will be treated with radiotherapy for cancer in the oropharynx. De radiation damage to the salivary system after radiotherapy, that aims to spare the parotid glands and one submandibular gland, will be assessed using questionnaires, flow measurements and MR imaging.

The prevalence of xerostomia in this group will be compared with that in a historical control group in which only the parotid glands were spared and that received the same questionnaires and flow measurements.

Study burden and risks

The burden associated with participation consists of salivary flow measurements, questionnaires and MRI measurements is relatively low. No risks are associated with these additional measurements and we try to avoid that patients have an extra visit to the hospital.

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 treated with radiotherapy for squamous cell carcinoma of the oropharynx.

Exclusion criteria

Previous radiotherapy of the salivary glands
Previous surgery of the salivary glands
Malignancies or other diseases of the salivary glands
TNM stages N2c and N3
Distant metastatic disease

Study design

Design

Study phase:	3
Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-02-2009
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	13-01-2009
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL23117.041.08