Prospective study for the changes in oral microflora and the composition of salivary proteins in patients, who receive radiation therapy for a tumor in the head and neck area.

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The objective of the study is to map the changes in the composition of salivary proteins as a consequence of irradiation of the salivary glands, to study how the composition of oral microflora changes as a consequence of irradiation and whether it...

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON33881

Source ToetsingOnline

Brief title

Changes in oral microflora and salivary proteins in irradiated patients.

Condition

Other condition

Synonym dry mouth, hyposalivation

Health condition

mondafwijkingen

Research involving Human

Sponsors and support

Primary sponsor: GABA Benelux Source(s) of monetary or material Support: bedrijf

Intervention

Keyword: fluoride, hyposalivation, oral microbiology, salivary proteins

Outcome measures

Primary outcome

composition of salivary proteins, microbial composition of saliva and plaque,

DMFS (decayed, missing, filled surfaces)/DMFT (decayed, missing, filled teeth)

scores, bleeding on probing scores

Secondary outcome

not applicable

Study description

Background summary

5% of all new tumors in the Netherlands is lokalised in the head and neck area. The incidence is increasing. The treatment strategy for this kind of tumors usually consists of surgery, often in combination with radiation. Irradiation of the head and neck area has a lot of side effects in the oral cavity. One of the frequent side effects is the onset of a dry mouth because irradiated glandulartissue dies and not enough saliva is being produced. Speech, swallowing and mastication are hampered. Furthermore the oral health seriously declines. Patients can develop rampant caries. The current preventive measurements are not yet sufficient. In the future there is a need for good preventive measurements that can slow down the onset of caries. At this moment the knowledge about the role of salivary proteins and oral bacteria in developing rampant caries is limited.

Study objective

The objective of the study is to map the changes in the composition of salivary proteins as a consequence of irradiation of the salivary glands, to study how the composition of oral microflora changes as a consequence of irradiation and whether it is possible to influence that in a positive way.

Study design

The study has a prospective, single-blind, randomized, controlled design.

Intervention

group A brushed there teeth twice a day with a fluoride toothpaste of there choice and applies a 0.45% neutral fluoride gel in a customized tray once every two days.

group B brushes there teeth twice a day with Meridol toothpaste and rinses additionally twice a day with Meridol mouthrinse.

Study burden and risks

The burden for participants exists of 4 appointments of 30 mintes in which saliva (total saliva and parotid saliva) and plaque are sampled. Furthermore they have to stick to the prescribed oral hygiene protocol and write down every week how often they used the prescribed products.

The risk for participants are assessed as very low, due to the fact that there are no known side effects of the prescribed oral hygiene protocols.

Contacts

Public GABA Benelux

Leeuwenveldseweg 5N 1382 LV Weesp NL **Scientific** GABA Benelux

Leeuwenveldseweg 5N 1382 LV Weesp NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age Adults (18-64 years) Elderly (65 years and older)

Inclusion criteria

-Curative irradiation of the head and neck area with a prescription dose of 56 Gy or more
- Target areas of irradiation at least bilateral neck at the height of level II
- At least one to two posterior elements on the side of the mouth that receives most radiation (elements that must be extracted for treatment are not included)
- Age > 18 years

Exclusion criteria

-previous treatment for a tumor in the head and neck area -surgical removal of (part of) the parotid gland

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-09-2009
Enrollment:	50
Туре:	Anticipated

Ethics review

Approved WMO	
Date:	21-01-2010
Application type:	First submission
Review commission:	PTC Stichting het Nederlands Kanker Instituut - Antoni van Leeuwenhoekziekenhuis (Amsterdam)

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 CCMO **ID** NL25236.031.09