The effects of radioiodine treatment on caries incidence in patients with differentiated thyroid carcinoma

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Primary Objectives 1. Evaluate whether the incidence of caries increases after radioiodine treatment as compared to the pre I131-therapy period in patients with differentiated thyroid carcinoma.Secondary Objectives 1. Evaluate whether the cumulative...

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

Summary

ID

NL-OMON50290

Source
ToetsingOnline

Brief title
Radioiodine and caries in DTC

Condition

- Other condition
- Thyroid gland disorders

Synonym
cavities, tooth decay

Health condition

caries

Research involving
Human

Sponsors and support

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

Intervention

Keyword: caries, differentiated thyroid carcinoma, hyposalivation, radioiodine therapy

Outcome measures

Primary outcome

The main study parameter is difference in the rate of incident carious lesions before and after radioiodine therapy. Incident carious lesions are defined as reported new developed carious lesions in the dental record, a dental restoration or a tooth extraction.

Secondary outcome

Secondary study parameters:

1. Unstimulated and stimulated saliva pH

2. Flow rate of unstimulated and stimulated saliva in ml/min

3. Cumulative radioiodine dose

4. Number of radioiodine treatments

5. Xerostomia questionnaire score

6. Dental care questionnaire score

7. DPSI score (Dutch Periodontal Screening Index score)

Other study parameters include:

1. Baseline characteristics: age, sex, tumour histology and TNM classification.

2. Medication list

Study description

Background summary

Patients with differentiated thyroid carcinoma (DTC) have a favourable prognosis, therefore there is a growing interest for late effects of treatment. Radioiodine (I131) therapy is one of the standard treatment entities for DTC patients. I131 treatment has been associated with salivary gland damage, and many patients have complaints of a dry mouth. Except for complaints of xerostomia, several patients in follow-up for DTC in the UMCG presented with a highly increased incidence of caries. In these patients the caries episode started after DTC diagnosis/I131 therapy, therefore will study the effects of I131 treatment on the development of dental caries.

A cross-sectional study with DTC patients in follow-up for at least 4 years will give us more guidance in the magnitude of this problem. The study can reveal predictors to identify patients at risk for development of new carious lesions, and contribute to prevent long-term adverse effects of treatment and improve care for DTC survivors.

Study objective

Primary Objectives
1. Evaluate whether the incidence of caries increases after radioiodine treatment as compared to the pre I131-therapy period in patients with differentiated thyroid carcinoma.

Secondary Objectives
1. Evaluate whether the cumulative radioiodine dose, saliva flow rate, saliva pH and xerostomia complaints are predictors for the development of dental caries after radioiodine treatment in differentiated thyroid carcinoma patients.
2. Evaluate whether there is a site-specific pattern for caries in differentiated thyroid carcinoma patients.

Study design

Cross-sectional exploratory observational study

Study burden and risks

This study is not associated with any risks for the participating patient. Furthermore, the burden of study participation is low, as study participation takes only 30 minutes, and study measurements take place directly after a outpatient visit. There are no invasive measurements or interventions.

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

- age at time of the first I131 treatment is at least 26 years
- the patient is diagnosed with DTC at least 4 years ago
- the patient has been treated with I131
- the patient visits a dentist and is dentate at the time of I131 treatment
- the subject gives written informed consent for study participation

Exclusion criteria

- a history of Sjögren*s syndrome or other salivary gland disease affecting salivary gland function
- the patient switched dentist in the period of 4 years before and 4 years

after the first radioiodine therapy, with no (complete) transfer of the dental record.
- the patient didn*t visit his/her dentist in the in the period of 4 years before and 4 years after radioiodine therapy.
- patient is mentally incapacitated

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-02-2014
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	22-01-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Approved WMO

Date:	28-04-2020
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 29082
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL45875.042.13
Other	NTR candidate number 15889
OMON	NL-OMON29082