Adverse effects of radioiodine treatment on salivary glands in differentiated thyroid carcinoma patients

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Primary Objectives 1. To assess whether radioiodine therapy results in hyposalivation, altered saliva composition and xerostomia in DTC patients.2. To assess whether the extent of radioiodine uptake on the pre- and post-therapy WBS and SPECT/CT is...

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

Summary

ID

NL-OMON40486

Source
ToetsingOnline

Brief title
Radioiodine and salivary glands

Condition

- Other condition
- Thyroid gland disorders

Synonym
inflammation of a salivary gland due to radioiodine therapy, sialoadenitis

Health condition

sialoadenitis

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: Differentiated thyroid carcinoma, Radioiodine therapy, Salivary glands, Xerostomia

Outcome measures

Primary outcome

The main study parameter is difference in stimulated salivary flow rate before

and after radioiodine therapy, for 1) whole saliva and 2) glandular saliva.

Other main study parameters:

- Difference in parameters before and after radioiodine therapy:

o Whole saliva flow rate (unstimulated)

o Sialochemistry (sodium, potassium, chloride, amylase, total

protein)

- Unstimulated whole saliva

- Stimulated whole saliva

- Stimulated glandular saliva

- Left parotid saliva

- Right parotid saliva

- Submandibular/sublingual saliva

- The correlation between:

o Semi-quantitative radioiodine uptake in salivary glands on the

pre-therapy WBS and difference in stimulated saliva flow rates

pre/post I-131

o Semi-quantitative radioiodine uptake in salivary glands on the

post-therapy WBS and difference in stimulated saliva flow rates

pre/post I-131

o Quantitative radioiodine uptake in salivary glands on the

SPECT/CT and difference in stimulated saliva flow rates pre/post I-131

Secondary outcome

Secondary study parameters:

- Difference in Xerostomia Inventory score (questionnaire) before and

after radioiodine therapy

- Correlation between post-therapy Xerostomia Inventory score and

difference in stimulated saliva flow rates pre/post I-131

- Difference in stimulated salivary flow rates in patients with 1

radioiodine cycle as compared with patients with 2 or more radioiodine

cycles

- Correlation between cumulative radioiodine dose and post-therapy

stimulated saliva flow rates

Study description

Background summary

Differentiated thyroid carcinoma (DTC) is a malignancy with a favorable survival in the majority of patients. Therefore the adverse effects of DTC treatment have gained more interest. Radioiodine (I-131) therapy is a standard therapy for patients with DTC. Salivary glands are known to concentrate (radio)iodine and are therefore at risk for damage following I-131 therapy, which can result in decreased saliva flow (hyposalivation) and oral dryness

(xerostomia). Several studies assessed salivary gland function by salivary gland scintigraphy. However, no studies assessed salivary gland specific saliva flow and gland specific saliva composition, while these measures directly reflect damage to the particular salivary gland.

Study objective

Primary Objectives
1. To assess whether radioiodine therapy results in hyposalivation, altered saliva composition and xerostomia in DTC patients.
2. To assess whether the extent of radioiodine uptake on the pre- and post-therapy WBS and SPECT/CT is predictive for post-therapy hyposalivation, alterations in saliva composition and xerostomia.

Secondary Objectives
1. To assess whether outcome of the validated xerostomia inventory questionnaire correlates with objective saliva flow rate and composition parameters.
2. To assess when the major salivary gland damage occurs; after the first radioiodine cycle or is there increasing damage with increasing cumulative radioiodine dose or number of radioiodine cycles?

Study design

Multicenter prospective observational study

Study burden and risks

The study is without risks for patients, as the saliva collection procedure is non-invasive. All nuclear scans used in this study are part of standard care.

Patients may benefit from the study. In case the patient has hyposalivation and complaints of xerostomia, the patient gets advice on how to reduce complaints and keep a good oral health. If indicated, lubricating agents or more specialized medical care will be advised.

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

1. Age at diagnosis is at least 18 years
2. The patient is awaiting radioiodine ablation therapy following DTC diagnosis, or is in follow-up for DTC and awaiting radioiodine therapy for persistent or recurrent disease
3. The subject gives written informed consent for study participation

Exclusion criteria

1. A history of Sjögrens syndrome or other salivary gland disease affecting salivary gland function
2. Oral ulceration
3. Patient is mentally incapacitated
4. Patient receives recombinant human TSH (rhTSH) prior to I131 treatment

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-05-2013
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	07-05-2013
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	12-08-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	18-10-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	23-04-2014
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: 24390
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL42972.042.13
OMON	NL-OMON24390