Adverse effects of radioiodine treatment on salivary glands in patients with thyroid cancer

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	-

Summary

ID

NL-OMON24390

Source
Nationaal Trial Register

Brief title
N/A

Health condition

Salivary glands
Differentiated thyroid carcinoma (DTC)
Radioiodine therapy (I131)

Sponsors and support

Primary sponsor: T.P. Links, University Medical Center Groningen
Source(s) of monetary or material Support: T.P. Links, this research is funded by an MD/PhD bench fee.

Intervention

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) in:
- Unstimulated whole saliva
- Stimulated whole saliva
- Stimulated glandular 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 and post I-131 therapy
o Semi-quantitative radioiodine uptake in salivary glands on the post-therapy WBS and difference in stimulated saliva flow rates pre and post I-131 therapy
o Quantitative radioiodine uptake in salivary glands on the SPECT/CT and difference in stimulated saliva flow rates pre and post I-131 therapy

Secondary outcome

- 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

N/A

Study objective

N/A

Study design

DTC patients visit the outpatient clinic twice for study visits. The first visit is before the I131 therapy, the second approximately 5 months after I131 therapy.

Intervention

Observational study

Patients visit the outpatient clinic twice for study visits. The following measurements are performed:

- Patients fill out the xerostomia inventory questionnaire

- Whole unstimulated and chewing stimulated saliva is collected

- Thereafter, gland specific (stimulated) saliva is collected

Futhermore, the iodine uptake is measured (semi) quantitatively on the pre therapy whole body scan (WBS), the post therapy WBS and the post therapy SPECT/CT.

Contacts

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Eligibility criteria

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 patient 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

Study design

Design

Intervention model: Other
Control: N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	13-05-2013
Enrollment:	80
Type:	Anticipated

Ethics review

Positive opinion

Date:	17-12-2013
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 40486
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4113
NTR-old	NTR4354
CCMO	NL42972.042.13
ISRCTN	ISRCTN wordt niet meer aangevraagd
OMON	NL-OMON40486

Study results

Summary results
N/A