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

Gepubliceerd: 17-12-2013 Laatst bijgewerkt: 15-05-2024

N/A

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	-

Samenvatting

ID

NL-OMON24390

Bron
NTR

Verkorte titel
N/A

Aandoening

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

Ondersteuning

Primaire sponsor: T.P. Links, University Medical Center Groningen
Overige ondersteuning: T.P. Links, this research is funded by an MD/PhD bench fee.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

N/A

Doel van het onderzoek

N/A

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. A history of Sjögrens syndrome or other salivary gland disease affecting salivary gland

function

2. Oral ulceration

3. Patient is mentally incapacitated

Onderzoeksopzet

Opzet

Onderzoeksmodel: Anders
Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	13-05-2013
Aantal proefpersonen:	80
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	17-12-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 40486
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A