

Ablation therapy in differentiated thyroid cancer with recombinant TSH.

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON23578

Bron

NTR

Verkorte titel

Links I 131 ablation

Aandoening

gedifferentieerd schildkliercarcinoom
differentiated thyroid cancer
ablation therapy
ablatie therapie
recombinant TSH
thyroid hormone withdrawal
schildklierhormoon onttrekking
I-131 therapie

Ondersteuning

Primaire sponsor: Prof.dr. T.P. Links, endocrinologist

Overige ondersteuning: unrestricted grant : Genzyme

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Successful ablation defined as: rhTSH Tg<1ng/ml, negative rhTSH dx WBS, negative US and negative Tg antibodies.

Toelichting onderzoek

Achtergrond van het onderzoek

This study is determining the rate of ablation failure in differentiated thyroid cancer patients using rhTSH instead of thyroid hormone withdrawal for stimulation of remnant tissue, using a fixed dosage of 3.7 GBq in T1b-T3 N0N1M0 patients.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Study procedures:

After total thyroidectomy and histological confirmation of differentiated thyroid cancer substitution therapy is started (levothyroxine) to reach a TSH level < 0.3 mU/l.

3-6 WEEKS post surgery:

Neck ultrasound (standard application) to confirm the absence of significant thyroid remnant and to screen for lymph nodes. Basal TSH and Tg measurement.

6 WEEKS post surgery:

0.9 mg rhTSH will be administered i.m. at 0 and 24 hours.

At 48 hours 3.7 GBq (100 mCi) I-131 will be administered.

Post treatment scan 7 - 10 days after I-131 application. TSH and Tg measurement at 48 hours. To ensure the I-deficient diet (according to the Dutch guidelines), the iodine excretion in a 24 hours urine will be measured (in µg/l).

6 MONTHS post ablation therapy:

Neck ultrasound and FNA of suspected nodules (if positive consider re-surgery).

9 MONTHS post ablation therapy:

0.9 mg rhTSH will be administered i.m. at 0 and 24 hours (Monday and Tuesday). At 48 hrs 150 MBq (4 mCi) I-131 application (Wednesday). TSH and Tg measurement and WBS 72 hours (Friday) after administration of 150 MBq (4 mCi) I-131 (i.e. 120 hours after the first rhTSH). (In case of visible uptake on a planar view, then a SPECT view will be made if available).

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Low and high risk patients (according American Joint Committee on Cancer, AJCC 6) with recently diagnosed histological proven DTC, who have to be treated with ablation therapy. TNM stages T1>1cm, T2, T3, N0, N1, M0 are to be included;

2. Aged 18 years or older;
3. Not pregnant;
4. No major concurrent diseases (such as instable cardiovascular disease, concurrent malignancy treated <5 years);
5. Normal renal function (serum creatinine level <130 umol/l or clearance > 40ml/min);
6. No iodine containing medication or recent history of iodine containing imaging contrast agents;
7. Male and female.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Stage T4;
2. Stage M1 when known before ablation;
3. Stage M1 known after ablation (remove from sequential analysis);
4. Tg antibodies positive at diagnosis;
5. Undetectable Tg during rhTSH stimulation at the time of ablation therapy (remove from sequential analysis).

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	15-06-2010
Aantal proefpersonen:	144
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	29-06-2010
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2269
NTR-old	NTR2395
Ander register	UMC Groningen : METC 2009/199
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A