Ablation therapy in differentiated thyroid cancer with recombinant TSH.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23578

Source
NTR

Brief title
Links I 131 ablation

Health condition

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

Sponsors and support

Primary sponsor: Prof.dr. T.P. Links, endocrinologist
Source(s) of monetary or material Support: unrestricted grant : Genzyme

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

N/A

Study description

Background summary

This study is determing 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 inT1b-T3 N0N1M0 patients.

Study design

N/A

Intervention

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).

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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).

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-06-2010
Enrollment:	144
Type:	Anticipated

Ethics review

Positive opinion

Date:	29-06-2010
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

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

Study results

Summary results

N/A