Shortened treatment strategy in patients with differentiated thyroid cancer.

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By reducing the interval between thyroidectomy and radioiodine ablation therapy in patients sick leave time of the patients can be reduced and the quality of life improved. Furhermore costs will for society will be lower.

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

Samenvatting

ID

NL-OMON21104

Bron
NTR

Verkorte titel
FASTHYNA

Aandoening

Differentiated thyroid cancer.

Ondersteuning

Primaire sponsor: UMC Utrecht
Overige ondersteuning: not applicable

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Days of sick leave reported from time of surgery.

Toelichting onderzoek

Achtergrond van het onderzoek

The initial treatment of patients with differentiated thyroid cancer (DTC) consists of total thyroidectomy followed by thyroid remnant radioiodine ablative therapy (RIT). For successful RIT, elevated levels of thyroid stimulating hormone (TSH) are required. Before the introduction of recombinant human TSH (rhTSH) patients were withheld thyroid hormone substitution therapy for 4 weeks after surgery. Nowadays RIT after rhTSH admission is possible, preventing thyroid hormone withdrawal and subsequent symptoms of hypothyroidism in these patients. Results of RIT after thyroid hormone withdrawal and rhTSH stimulation are comparable. RIT with rhTSH stimulation allows planning of the RIT shortly after thyroidectomy.

We hypothesize that with the availability of rhTSH the treatment of DTC patients in a fast track protocol, i.e. RIT shortly after thyroidectomy, will reduce sick leave time, which will lead to a cost reduction for society, and secondly that the fast track treatment will lead to a higher quality of life for the patients during treatment. Patients will be sooner ‘back on track’. In this way both society and patients will benefit from the implementation of the fast track protocol.

Doel van het onderzoek

By reducing the interval between thyroidectomy and radioiodine ablation therapy in patients sick leave time of the patients can be reduced and the quality of life improved. Furhermore costs will for society will be lower.

Onderzoeksopzet

Continuous monitoring of sick leave and quality of life from start of treatment until 2 months after therapy.

Onderzoeksproduct en/of interventie

Standard treatment: Thyroidectomy followed by a 4-6 week during waiting period and then ablation with radioactive iodine.

Interventional treatment: Thyroidectomy directly followed by radioactive iodine ablation.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients with proven differentiated thyroid cancer, stage T1-3N0-1M0;

2. Planned for total or completion thyroidectomy;

3. Paid job; at least 12 hours per week;

4. Capable of understanding Dutch questionnaires and keeping a diary.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Pregnant or breastfeeding patients;

2. T4 (i.e. tumor expansion in vital structures) or M1 tumors;

3. Contrast enhanced CT performed < 4 months prior to inclusion;

4. Hypersensitivity to bovine serum albumin, rhTSH or to any of the excipients;

5. Dialysis-dependent end stage renal disease.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-05-2013
Aantal proefpersonen:	58
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	03-04-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 39885
Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3747
NTR-old	NTR3933
CCMO	NL41880.041.13
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON39885

Resultaten

Samenvatting resultaten
N/A