

Shortened treatment strategy in patients with differentiated thyroid cancer.

No registrations found.

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

Summary

ID

NL-OMON21104

Source

NTR

Brief title

FASTHYNA

Health condition

Differentiated thyroid cancer.

Sponsors and support

Primary sponsor: UMC Utrecht

Source(s) of monetary or material Support: not applicable

Intervention

Outcome measures

Primary outcome

Days of sick leave reported from time of surgery.

Secondary outcome

1. Quality of life;

2. Costs associated with productivity at work;
3. Societal costs associated with absence from work.

Study description

Background summary

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.

Study objective

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. Furthermore costs will for society will be lower.

Study design

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

Intervention

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.

Contacts

Public

Huispost nummer G04.228

UMC Utrecht

Postbus 85500
J.W. Kist
Utrecht 3508 GA
The Netherlands
+31 (0)6 41853004

Scientific

Huispost nummer G04.228

UMC Utrecht

Postbus 85500
J.W. Kist
Utrecht 3508 GA
The Netherlands
+31 (0)6 41853004

Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-05-2013
Enrollment:	58
Type:	Anticipated

Ethics review

Positive opinion	
Date:	03-04-2013
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 39885
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

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

Study results

Summary results

N/A