Fast-track thyroidectomy and radioiodine ablation therapy in patients with differentiated thyroid cancer.

Published: 26-08-2013
Last updated: 19-03-2025

This study aims to detect differences in sick leave time, associated costs and quality of life between differentiated thyroid cancer patients treated in either a fast-track protocol or a traditional longer time interval between total thyroidectomy...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Thyroid gland disorders
Study type	Observational non invasive

Summary

ID

NL-OMON39885

Source
ToetsingOnline

Brief title
FASTHYNA trial

Condition

- Thyroid gland disorders
- Endocrine neoplasms malignant and unspecified

Synonym
Differentiated thyroid cancer

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Subsidie van Genzyme;producent van rhTSH

Intervention

Keyword: Differentiated thyroid cancer, Fast-track protocol, Quality of life, Sick leave

Outcome measures

Primary outcome

Days of sick leave reported from time of surgery

Secondary outcome

Quality of life

Costs associated with productivity at work

Societal costs associated with absence from work

Study description

Background summary

The initial treatment of patients with differentiated thyroid cancer consists of total thyroidectomy followed by thyroid remnant radioiodine ablative therapy (RIT). For successful RIT, elevated TSH levels are necessary. Before the introduction of recombinant human TSH (rhTSH) patients were withheld thyroid hormone substitution therapy for 4 weeks after surgery. Nowadays RIT after rhTSH 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. The availability of rhTSH resulted in the possibility to plan the ablation directly after the surgery.
We hypothesize that with the availability of rhTSH the waiting period post operatively can be shortened and that with a fast track protocol treatment of thyroid cancer patients will result in less sick-leave time. Secondly, patients will have a higher quality of life during the treatment, the costs of the fast-track protocol for society will be less.

Study objective

This study aims to detect differences in sick leave time, associated costs and quality of life between differentiated thyroid cancer patients treated in either a fast-track protocol or a traditional longer time interval between

total thyroidectomy and rhTSH aided RIT.

Study design

Randomized prospective multicenter study

Intervention

58 patients will be randomly allocated to either A) thyroidectomy directly followed by RIT (fast-track protocol (n=29), or B)
thyroidectomy followed by a 4 week waiting period before RIT (standard treatment protocol (n=29)).

Study burden and risks

The risk of this study for the subjects will be minimal because the intervention treatment protocol is in general identical to the standard treatment according to the national guidelines. The subjects allocated to the intervention group (group 1) will benefit from the new *fast-track* protocol. Subjects in the standard treatment group (group 2) will not have a different treatment compared to not participating patients.
The burden consists of extra questionnaires and a diary. This is considered to be minimally.
The result of this study will substantially reduce both the duration of the treatment for patients with DTC as the costs of this treatment for society in the future. This justifies the minimal extra burden on the subjects included in this study.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3508GA
NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3508GA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. Patients with differentiated thyroid cancer, stage T1-3N0-1M0-x
2. Patient 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 other of the excipients
5. Dialysis-dependent end stage renal disease

Study design

Design

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

Primary purpose: Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-11-2013
Enrollment:	58
Type:	Actual

Ethics review

Approved WMO Date:	26-08-2013
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	10-06-2014
Application type:	Amendment
Review commission:	METC NedMec

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 21104
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL41880.041.13
OMON	NL-OMON21104