

I-131 remnant ablation in differentiated thyroid cancer-optimal treatment with maximal outcome

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To determine that rhTSH pretreatment during euthyroidism (already available in a number of centres in the Netherlands) in a adequately powered study is as good as the classical way of inducing hypothyroidism by withholding suppletion which induces...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Thyroid gland disorders
Study type	Interventional

Summary

ID

NL-OMON36661

Source

ToetsingOnline

Brief title

rhTSH stimulated remnant ablation in differentiated thyroid cancer

Condition

- Thyroid gland disorders

Synonym

differentiated thyroid carcinoma, thyroid cancer

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: Genzyme, Genzyme Corporation

Intervention

Keyword: ablation, cancer, remnant, thyroid

Outcome measures

Primary outcome

The primary endpoint of successful ablation is defined as: rhTSH Tg<1ng/ml, negative rhTSH dx WBS, negative neck US and negative Tg antibodies.

In case of TgAb or Tg < 1 ng/ml at the time of ablation, a second high dose of I131 will be given according to the Dutch guidelines. In these patients a successful ablation will be defined as a post treatment scintigraphy with no visible uptake in the original thyroid bed

Secondary outcome

not applicable

Study description

Background summary

Patients with differentiated thyroid cancer (papillary and follicular) are treated with near-total thyroidectomy. In most of the patients this treatment has to be followed by ablation with I-131 to eliminate remnant thyroid tissue to decrease the risk of tumor recurrence and improve sensitivity and specificity of thyroglobulin measurement in follow-up.

Study objective

To determine that rhTSH pretreatment during euthyroidism (already available in a number of centres in the Netherlands) in an adequately powered study is as good as the classical way of inducing hypothyroidism by withholding supplementation which induces endogenous rise of the TSH level.

Study design

Prospective observational study design, to evaluate an international accepted but not in all treating centers applied therapy.

Intervention

Two rhTSH injections will be given 6 weeks after total thyroidectomy (before 131-I treatment) and 9 months after the first high dose 131-I treatment.

Study burden and risks

After thyroidectomy immediately start with suppletion

After 4 weeks on 2 days in succession 1 injection with rhTSH

After 9 months on 2 days in succession 1 injection with rhTSH

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

low and high risk patients (AJCC 6) with recently diagnosed histological proven differentiated thyroid cancer, who have to be treated with ablation therapy

aged 18 years or older

not pregnant

not major concurrent diseases (such as stable cardiovascular disease, concurrent malignancy treated < 5 years) leading to a reduced survival < 1 year

normal renal function

Exclusion criteria

Stage T4

Stage M1 when known before ablation

Study design

Design

Study type: Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

Recruitment

NL

Recruitment status: Will not start

Start date (anticipated): 01-10-2009

Enrollment: 144

Type: Anticipated

Ethics review

Approved WMO

Date: 23-10-2009

Application type: First submission

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

Approved WMO

Date: 20-09-2011

Application type: Amendment

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

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
CCMO	NL28778.042.09