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

Published: 23-10-2009
Last updated: 06-05-2024

To determine that rhTSH pretretament during euthyroidism (already available in an number of centra in the Netherlands) in a adequately powered study is as good as the classical way of inducing hypothyrodism 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 tthe time of ablation, a second high dose of

I131 will be given according to the Dutch guidelines. In these patients a

succesfull 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 pretretament during euthyroidism (already available in an number of centra in the Netherlands)
in a adequately powered study is as good as the classical way of inducing hypothyrodism by withholding suppletion which induces endogeneous rise of the TSH level.

Study design

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

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
9713 GZ Groningen
NL
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1
9713 GZ Groningen
NL

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