PTH after total thyroidectomy,a predictive factor for long-term hypoparathyroidism?

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The aim of our study is to investigate whether PTH levels measured between 4-24 hours after surgery can accurately identify patients with permanent hypoparathyroidism after thyroid surgery who need long-term calcium supplementation.

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

Summary

ID

NL-OMON38463

Source
ToetsingOnline

Brief title
PTH after total thyroidectomy

Condition

- Thyroid gland disorders

Synonym
hypoparathyroidism

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: calcium supplementation, hypoparathyroidism, parathyroidhormone, Thyroidectomy

Outcome measures

Primary outcome

Can we use PTH levels obtained directly after surgery to predict which patient

will remain hypocalciaemic?

Secondary outcome

Not applicable

Study description

Background summary

Total thyroidectomy is the operation of choice for many patients with thyroid carcinoma, and sometimes with Graves* disease or multinodular goitre. Postoperative hypoparathyroidism, following total thyroidectomy is a common iatrogenic complication leading, among other factors, to hypocalcaemia. Up to 55-60% of the patients develop serum calcium levels below 2.00 mmol/L on the first day after surgery. Therefore it is routine practice to monitor patients clinically for signs and symptoms of hypocalcaemia as well as perform regular measurements of serum calcium levels. Recent studies (2,3) have shown that a serum parathyroid hormone (PTH) concentration obtained 4-24 hours postoperatively is the most significant factor to predict postoperative hypocalcaemia. In most patients with post-thyroidectomy hypocalcaemia, parathyroid function (if any glands are left) restores within several weeks. However, up to 5-10% of the patients may develop persistent hypoparathyroidism and require lifelong calcium supplementation. In a study by Sitges-Serra et al.1 evaluating 442 patients after total thyroidectomy, 222 patients had postoperative hypocalcaemia. Of them, 40% (80/222 patients) still had hypocalcaemia one month after surgery. PTH levels were also measured one month after surgery: 90% (40/44 patients) of the patients with low PTH levels recovered to normal parathyroid function within one year compared with 62% of the patients with undetectable parathyroid levels (21/34 patients). Logistic regression analysis identified undetectable PTH levels one month after surgery to predict permanent failure of parathyroid function. However, PTH levels directly after surgery were not measured. We aim to identify a predictive

factor for persistent hypoparathyroidism after a total (or completion) thyroidectomy that can be obtained directly after surgery. This would not only be valuable for planning outpatient appointments, but would also provide more certainty for the patient. In addition calcium supplementation can become more patient tailored at the outpatient department, aiming to reduce the negative consequences of hypocalcaemia, unnecessary visits and laboratory investigations. Therefore the aim of our study is to investigate whether PTH levels measured between 4-242,3 hours after surgery will identify patients who need long-term calcium supplementation.

Study objective

The aim of our study is to investigate whether PTH levels measured between 4-24 hours after surgery can accurately identify patients with permanent hypoparathyroidism after thyroid surgery who need long-term calcium supplementation.

Study design

This extra protocol applies to all patients who have given informed consent.
1. Prior to surgery (outpatient department), (Day -1)
a. Check informed consent and contact with study coordinator
b. Lab (t=0): Routine laboratory screening, including: calcium/ phosphate/albumin/vitamin D including: PTH for the study
2. Day of surgery (Day = 0)
a. Lab (t=1 / 18:00): Routine laboratory screening (calcium, phosphate, albumin, vitamin D), including: PTH for the study
3. Day after surgery (Day = +1)
a. Lab (t=2 / 08:00): Routine laboratory screening (calcium, phosphate, albumin), including: PTH for the study
4. 1-2 weeks after surgery
a. Lab (t=3): Routine laboratory screening (calcium, phosphate, albumin), including: PTH for the study
5. 1 year after surgery
a. Lab (t=4): Routine laboratory screening (calcium, phosphate, albumin), including: PTH for the study
Interpretation of laboratory findings and calcium supplementation are based on the existing protocol (Attachment 1) which is not changed for the purpose of the study.

Study burden and risks

not applicable.

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

All patients scheduled for a total thyroidectomy (or subtotal if the istmus is to remain in situ) or completion thyroidectomy are to be included in this study.

Exclusion criteria

Patients undergoing concomitant lymph node dissection may also be included in the study.
o Age < 18
o Unable to provide informed consent
o Pre-operative disorders in calcium homeostasis: hypo/hypercalcaemia with/without calcium supplementation

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2013
Enrollment:	220
Type:	Anticipated

Ethics review

Approved WMO

Date:	11-02-2014
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL43050.078.12