Validation and feasibility assessment of STAT-intraoperative-PTH measurement during total thyroidectomy to predict postoperative hypocalcaemia

Published: 19-12-2019
Last updated: 09-04-2024

The aim of this study is to evaluate the use of rapid IO-PTH measurement to predict post-thyroidectomy hypocalciemia.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Endocrine neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON48460

Source
ToetsingOnline

Brief title
IO-PTH during Tx to predict hypocalcaemia

Condition

- Endocrine neoplasms malignant and unspecified

Synonym
Hypocalcaemia after thyroidectomy, low calcium levels after thyroid surgery

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W,Future Diagnostics

Intervention

Keyword: Hypocalcaemia, Predict, Thyroidectomy

Outcome measures

Primary outcome

postoperative serum calcium corrected for albumin levels.

Secondary outcome

- patient characteristics

- pre- intra- and postoperative PTH levels

- reported symptoms of hypocalcemia

- operation report

- pathology report

- length of hopsital stay

- type and dosage of calcium suppletion

Study description

Background summary

Hypocalcemia is the most common complication in patients undergoing total thyroidectomy. The cause of postoperative hypocalcemia is iatrogenic damage or resection of the parathyroid glands, which are anatomically closely related to the thyroid gland. Currently, postoperatively, calcium is only measured 6 hours after surgery and patients receive calcium suppletion when hypocalcaemia is detected or when the patient experiences symptoms. This causes a delay in treatment, and hospital stay is often prolonged. On the other hand, prophylactic calcium suppletion causes unnecessary overtreatment. Measuring the cause of hypocalcemia, hypoparathyroidism, during thyroid surgery, might provide a risk stratification of which patients will develop postoperative hypocalcemia and which will not. Intraoperative PTH measurement is currently only applied in parathyroid surgery, to determine the success of the operation. We would like to investigate the feasibility of using fast intra-operative PTH measurement to predict postoperative hypocalcemia. In the future, we might be

able to prevent hypocalcemia in patients who are determined at risk during thyroid surgery.

Study objective

The aim of this study is to evaluate the use of rapid IO-PTH measurement to predict post-thyroidectomy hypocalciemia.

Study design

Prospective cohort validation and feasibility study.

Study burden and risks

Burden: very low. 6x 6ml blood will be drawn during operation via standard i.v. access which every patient will receive.
Risks: no, there will be no consequences of the intraoperative findings. The surgery and/or postoperative treatment will not change.
Future patient will hopefully benefit from the findings of this study.

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

- Patients undergoing total thyroidectomy or;
- Patients undergoing completion thyroidectomy after previous hemithyroidectomy; and
- 25-OH vitamin D within the normal range
- *18 years and;
- Capable of understanding Dutch language and;
- Signed informed consent

Exclusion criteria

- Patients undergoing hemithyroidectomy
- Known parathyroid disease , e.g. hyperparathyroidism or hypoparathyroidism
- End-stage renal disease or kidney transplantation
- Use of calcium suppletion
- Use of lithium medication

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	50

Type:	Anticipated

Ethics review

Approved WMO Date:	19-12-2019
Application type:	First submission
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	NL69010.042.19
Other	UTOPIA201800653