*Implementation of a symptom based algorithm for calcium management after total thyroidectomy *

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The aim of this multi-centre study is to confirm the efficiency and safety of a new algorithm for calcium management after total thyroidectomy, primarily based on hypocalcemic symptoms.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Parathyroid gland disorders
Study type	Interventional

Summary

ID

NL-OMON45592

Source
ToetsingOnline

Brief title
IMPACT-trial

Condition

- Parathyroid gland disorders

Synonym
Hypocalcemia, hypoparathyroidism, low calcium bloodlevel

Research involving
Human

Sponsors and support

Primary sponsor: Maasstadziekenhuis
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Algorithm, Hypocalcemia, Thyroidectomy

Outcome measures

Primary outcome

The primary study endpoint is the difference in the percentage of patients

treated with calcium (and active vitamin D3-metabolite) supplements before and

after implementation of the new algorithm.

Secondary outcome

1. Number of readmissions for intravenous calcium supplementation

2. Number of calcium related contacts with the outpatient department

3. The incidence of hypocalcemia: both transient and permanent

4. Risk factors for hypocalcemia (patient or surgery related)

5. Incidence of hypocalcemic symptoms emerging after discharge

6. Complications related to hypocalcemia

7. Duration of admission

8. Number of patients requiring intravenous calcium supplementation

9. Relation between EKG abnormalities and hypocalcemia

Study description

Background summary

Hypocalcemia can occur in up to 27% of patients after total thyroidectomy mainly due to edema, ischemia or removal of parathyroid glands (PTGs). Treatment of hypocalcemia after total thyroidectomy is currently based on serum calcium and parathyroid hormone (PTH) levels. Unfortunately, there is no evidence-based guideline available. Recently a single centre study suggested patients can be treated safely and efficiently based solely on the occurrence

of hypocalcemic symptoms, irrespective of serum calcium levels. Based on this observation, a new treatment algorithm for hypocalcemia was developed for the Dutch clinical setting. This treatment algorithm is expected to optimise testing and treatment allocation and to reduce unnecessary calcium treatment. This will ultimately alleviate the burden for patients and results in lower health care costs.

Study objective

The aim of this multi-centre study is to confirm the efficiency and safety of a new algorithm for calcium management after total thyroidectomy, primarily based on hypocalcemic symptoms.

Study design

A prospective multi-centre implementation study of the new algorithm will be performed. After total thyroidectomy, all patients included in the study, will be treated according to this algorithm. Patients on calcium (and vitamin D metabolite) supplementation will receive instructions to phase out medication at home. The study population will be compared to a retrospective cohort of post-thyroidectomy patients operated before introduction of the new algorithm.

Intervention

New treatment algorithm

Study burden and risks

Patients will be asked to fill in hypocalcemic symptoms in a diary. The number of venepunctures during peri-operative care will not exceed current standard care, although extra tubes will be withdrawn during these venepunctures. Additionally, one extra EKG will be performed. The new treatment algorithm is primarily based on hypocalcemic symptoms. As noted earlier, a recent study treating only symptomatic patients, did not demonstrate serious complications associated with hypocalcemia. In our study an extra safety measurement is included: all patients will receive calcium supplementation irrespective of symptoms if the serum calcium level drops below 1.85 mmol/L. Furthermore patients will be carefully informed about hypocalcemic symptoms and will receive instructions what to do if these symptoms develop at home.
The number of patients treated with calcium supplements is expected to decrease due to the new algorithm. As a consequence the burden for patients will be alleviated in terms of the amount of visits to the outpatient clinic and discomfort associated with taking calcium supplements. Less patients will risk interaction of calcium supplementation with other medication, contributing to safe and efficient patient care.

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

1. Indication for total thyroidectomy or completion thyroidectomy
2. Patient age 18 years or older at the time of inclusion

Exclusion criteria

1. Pre-operative abnormal adjusted serum calcium level (reference range 2.20 -2.55 mmol/L)
2. Hyperparathyroidism
3. Planned parathyroidectomy
4. History of epileptic seizures
5. Pregnancy
6. Non dutch speaking

7. Not able to give informed consent

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	07-04-2017
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	22-02-2017
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL59859.101.16