Recurrent/persistent primary hyperparathyroidism, clinical, pathological and genetic aspects

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1. Characterization of patients with persistent and recurrent primary hyperparathyroidism after at least one parathyroidectomy, with removal of at least one pathological parathyroid gland.2. Evaluation of pre-operative localization studies;...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Parathyroid gland disorders
Study type	Observational invasive

Summary

ID

NL-OMON32114

Source
ToetsingOnline

Brief title
Recurrent/persistent primary hyperparathyroidism

Condition

- Parathyroid gland disorders

Synonym
hyperactive parathyroid glands, primary hyperparathyroidism

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Primary hyperparathyroidism, Recurrence/persistence

Outcome measures

Primary outcome

1. Clinical and biochemical parameters

2. Pre-operative localization studies; MiBi-SPECT, PTH sampling

3. Intra-operative PTH measurements

4. Operative data

5. Pathology data

6. DNA analysis on leukocytes, formaline fixed paraffine imbedded (FFPE) tissue

or frozen material

Secondary outcome

No secondary study parameters

Study description

Background summary

In a pilot study of patients with recurrent or persistent PHPT we have observed that they present with clinical characteristics clearly different from the majority of patients with PHPT who achieve cure. They are younger, have a more aggressive disease, with higher levels of serum calcium and PTH and more complications, such as osteoporosis and nefrolithiasis. MiBi-scan is poorly predictive of localization and intra-operative PTH has an abnormal pattern of disappearance from the circulation. This represents the rationale for further investigation of this group of patients compared with a control group of patients with cured PHPT post-parathyroidectomy based on clinical, diagnostic, pathological and genetic differentiating aspects of their disease.

Study objective

1. Characterization of patients with persistent and recurrent primary

hyperparathyroidism after at least one parathyroidectomy, with removal of at least one pathological parathyroid gland.
2. Evaluation of pre-operative localization studies; SestaMiBi-SPECT scanning and PTH sampling, in patients with recurrent/persistent PHPT vs cured control patients.
3. Evaluation of intra-operative PTH measurements (IOPTH), in patients with recurrent/persistent PHPT vs 5 year cured control patients.
4. Genetic characterization of patients with persistent/recurrent PHPT.
5. And in the process evaluate the real cure rate 1, 5 and 10 year after parathyroidectomy in a control group.

Study design

single-centre, two fold design, retrospective data analysis from; previous surgery, MiBi-SPECT, PTH sampling, IOPTH measurement, pathologic glands, and prospective analysis; pedigree construction, DNA analysis, pathological specification, simple blood analysis to ascertain the cure rate in recall control patients.

Study burden and risks

No risks involved

Benefits: Decreased morbidity attached to a re-exploration by early identification of patients with an increased risk of recurrence/persistence of primary hyperparathyroidism after parathyroidectomy

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

proven recurrent/persistent primary hyperparathyroidism after excision of one or more pathological parathyroid glands

Exclusion criteria

primary hyperparathyroidism due to MEN syndrome, lithium use or parathyroid carcinoma, secundary or tertiary (autonomous) hyperparathyroidism due to long time vitamin D deficiency or chronic renal failure

Study design

Design

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

Primary purpose: Basic science

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated):	22-12-2008
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	17-12-2008
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL23097.058.08