

Parathyroidectomy versus cinacalcet for the correction of secondary hyperparathyroidism in hemodialysis patients

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29506

Source

NTR

Brief title

RHINO trial

Health condition

The use of Cinacalcet in secondary hyperparathyroidism and chronic renal failure instead of Total parathyroidectomy

Sponsors and support

Primary sponsor: Kruijff S, Groningen, The Netherlands

Hanzeplein 1a , Surgical department

s.kruijff@umcg.nl

Source(s) of monetary or material Support: applications for funding still pending

Intervention

Outcome measures

Primary outcome

PTH 3 months after the intervention

Secondary outcome

- cardiovascular events (myocardial infarction, peripheral vascular disease, instable angina, cerebrovascular disease, CVA, TIA), arrhythmias)
- Costs
- phosphorus, calcium
- fibroblast growth factor 23 levels
- renal function
- all-cause mortality

Study description

Background summary

Secondary hyperparathyroidism (sHPT) is one of the most common abnormalities in patients with chronic kidney disease, and is characterized by parathyroid gland hyperplasia and increased plasma levels of parathyroid hormone (PTH). This condition results in disturbances in vitamin D, phosphorus, calcium and PTH metabolism and bone disorders and has been associated with cardiovascular complications increased mortality. Elevation of PTH higher than 300-450 pg/ml is associated with an increased all-cause mortality.

Since the introduction of Cinacalcet in 2004 the drug has changed global prescription patterns dramatically which shifted from surgery to dominantly medical treatment. However, cinacalcet has never been systematically compared with with (sub) total parathyroidectomy (PTx) and it has side effects (evolve trial 2012) is expensive and postpones definite treatment leading to morbidity.

Therefore the multicentre Rhino trial was initiated comparing PTx versus Cinacalcet.

Study objective

Total parathyroidectomy (PTX) in patients with secondary hyperparathyroidism (HPT2) is a more effective treatment than the use of Calcimimetica.

Study design

first interim-analysis after one year, follow up in study two years.

Intervention

Total parathyroidectomy with transplantation versus the use of Cinacalcet

Contacts

Public

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Eligibility criteria

Inclusion criteria

- Age > 18 years
- Newly diagnosed sHPT, defined as PTH level >9x ULN
- Hemodialysis or peritoneal dialysis patients
- > 3 months of chronic dialysis
- Signed informed consent

Exclusion criteria

- Cinacalcet use within the past 3 months
- Former renal transplant
- Former parathyroidectomy
- Former dialysis
- Malignancy in history

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-01-2016
Enrollment:	128
Type:	Anticipated

Ethics review

Not applicable	
Application type:	Not applicable

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
NTR-new	NL5266
NTR-old	NTR5382
Other	ZonMW : 55288

Study results