

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

Gepubliceerd: 25-08-2015 Laatste bijgewerkt: 18-08-2022

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

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON29506

Bron

NTR

Verkorte titel

RHINO trial

Aandoening

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

Ondersteuning

Primaire sponsor: Kruijff S, Groningen, The Netherlands

Hanzeplein 1a , Surgical department

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Overige ondersteuning: applications for funding still pending

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

PTH 3 months after the intervention

Toelichting onderzoek

Achtergrond van het onderzoek

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 (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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

Total parathyroidectomy with transplantation versus the use of Cinacalcet

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

-Malignancy in history

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2016
Aantal proefpersonen:	128
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing	
Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register

NTR-new

NTR-old

Ander register

ID

NL5266

NTR5382

ZonMW : 55288

Resultaten