

Efficacy of cinacalcet in hyperparathyroidism after renal transplantation.

No registrations found.

Ethical review	Not applicable
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24309

Source

NTR

Brief title

CHART

Health condition

open label observational study during 8 months in approx 20 renal transplant patients

Sponsors and support

Primary sponsor: Renal Transplant Unit

Academic Medical Center

Source(s) of monetary or material Support: none yet

Intervention

Outcome measures

Primary outcome

Normalisation of serum calcium and parathormon at six months.

Secondary outcome

Reduced and sustained parathormon activity after withdrawal of cinacalcet.

Study description

Background summary

Calcimimetics are yet not used extensively after renal transplantation. By this observational open label study we are interested whether cinacalcet is able to normalize hyperparathyroidism and accompanying hypercalcemia and to which extent this effect is permanent or just temporary.

Study objective

Cinacalcet is able to control hypercalcemia due to hyperparathyroidism after renal transplantation ergo avoiding surgical removal of parathyroid tissue without jeopardizing renal function or eliciting serious adverse events.

Study design

N/A

Intervention

Administration of start dose of 30 mg cinacalcet when inclusion criteria are met.
Weekly and later monthly monitoring of biochemical and clinical parameters.
Six month after inclusion and reaching stable state (normocalcemia) slowly withdrawal of cinacalcet.

Contacts

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Eligibility criteria

Inclusion criteria

1. Hypercalciemia more than 2,60 mmol/l;
2. Elevated iPTH plasma levels more than 15 pmol/l;
3. Renaltransplantation longer than 2 months and stable renal function for at least 2 weeks;
4. Older than 18 years;
5. No vit D deficiency.

Exclusion criteria

1. Antirejection therapy less than 4 weeks; prior to inclusion;
2. Pregnancy.

Study design

Design

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

Recruitment

NL
Recruitment status: Recruitment stopped
Start date (anticipated): 01-02-2006
Enrollment: 20
Type: Actual

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	NL538
NTR-old	NTR582
Other	: N/A
ISRCTN	NO ISRCTN (not randomized)

Study results

Summary results

N/A