

# Research to cost-effectiveness of paricalcitol of the treatment of secondary hyperparathyroidism at hemodialysis patients

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Pending
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON24822

### Source

NTR

### Brief title

KEPS

### Health condition

Chronic Renal Failure: chronisch nierfalen

Secondary Hyperparathyroidism: secundaire hyperparathyreoidie

Vitamin D: vitamine D

Paricalcitol: paricalcitol

## Sponsors and support

**Primary sponsor:** Sint Lucas Andreas ziekenhuis

**Source(s) of monetary or material Support:** Sint Lucas Andreas ziekenhuis

## Intervention

## Outcome measures

### Primary outcome

Effectiveness: measure the main PTH level

### Secondary outcome

Security

Main Calcium ( $\text{Ca}^{2+}$ )-level

Main Fosfaat (P)-level

Main Calcium-Fosfaatproduct ( $\text{Ca} \times \text{P}$ ) -level

Numbers of hypercalcemia episodes

Numbers of hyperphosphatemia episodes

Numbers of raised  $\text{Ca} \times \text{P}$  episodes

Bone-alkaline phosphatase (BAP), expressed as a Z-score

Costs

Total costs of the whole treatment:  
measuring the oral medication of phosphate-binders and calcimimetics.

## Study description

### Background summary

The inadequate treatment of secondary hyperparathyroidism can have severe consequences, for example hyperplastic parathyroid glands, renal osteodystrophy and cardiovascular diseases.

Paricalcitol (Zemlar®) is a recently introduced third generation vitamin D analogon. The treatment with paricalcitol could have several advantages to the treatment with the “old” vitamin D analogon: alfacalcidol (Etalpa®).

Paricalcitol should correct the parathormone (PTH) level faster and reduce the numbers of hypercalcemia episodes. The trial is limited and the database on this subject is small, so the question if paricalcitol is more effective than the "old" vitamin D analoga alfacalcidol and calcitriol is relevant. This trial compares paricalcitol with alfacalcidol, the most used vitamin D in the Netherlands. The treatment with paricalcitol is four times more expensive than the treatment with alfacalcidol. The trial that compares the effectiveness, security and the costs between paricalcitol and alfacalcidol will give a useful insight to optimize the treatment for hemodialysispatients with secondary hyperparathyroidism

### **Study objective**

Paricalcitol induce a more effective reduction of the PTH level compared to alfacalcidol at hemodialysispatients with secondary hyperparathyroidism

### **Study design**

PTH: Every 4 weeks inclusive the Baseline

Ca<sup>2+</sup> tot: Every 2 weeks inclusive the Baseline

Ca<sup>2+</sup> ion: Every 2 weeks inclusive the Baseline

Alb serum: Every 2 weeks inclusive the Baseline

P: Every 2 weeks inclusive the Baseline

Ca<sup>2+</sup> x P: Every 2 weeks inclusive the Baseline

Bone-AP: Baseline, month 6, month 12

Hb: Every 4 weeks

Ferritine: Every 4 weeks

Urea (BUN): Baseline, month 6, month 12

Creat: Baseline, month 6, month 12

CRP: Baseline, month 6, month 12

### **Intervention**

After randomisation two groups of hemodialysispatients will be separated. Group A gets treated with alfacalcidol and Group B with paricalcitol.

After six months will the groups switch.

## Contacts

### **Public**

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## Eligibility criteria

### **Inclusion criteria**

1. Hemodialysis patients older than 18 years
2. Secondary hyperparathyroidism

### **Exclusion criteria**

1. Severe hypercalcemia
2. Severe liver failure
3. Digoxin overdose

#### 4. Hypersensitive response to vitamin D or vitamin D overdose

## Study design

### Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-07-2008
Enrollment:	114
Type:	Anticipated

## Ethics review

Positive opinion	
Date:	11-06-2008
Application type:	First submission

## 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	NL1294
NTR-old	NTR1341
Other	:
ISRCTN	ISRCTN wordt niet meer aangevraagd

## Study results

### Summary results

N/A