Research to (cost)effectiveness of paricalcitol in the treatment of secondary hyperparathyroidism

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24070

Source
Nationaal Trial Register

Brief title
KEPS

Health condition

paricalcitol
NL
Paricalcitol

secondary hyperparathyroidism
NL
Secundaire hyperparathyreoidie

vitamin D
NL
Vitamine D

chronic renal disease
NL
Chronische nierinsufficientie

Sponsors and support

Primary sponsor: Het Sint Lucas Andreas ziekenhuis
Source(s) of monetary or material Support: Het Sint Lucas Andreas ziekenhuis

Intervention

Outcome measures

Primary outcome

Effectiveness: mean PTH level

Secondary outcome

- Safety

- Mean Calcium (Ca2+)-level

- Mean Phosphate (P)-level

- Mean Calcium-phosphate (Ca x P) product

- Incidences of hypercalcemia

- Incidences of hyperphosphatemia

- Number of elevated Ca x P

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

- Costs

- Medication costs of the vitamine D therapy.

- Included in the therapy are phosphate binders, calcimimetics, (darbe)poetine and ferric oxide

Study description

Background summary

An inadequate treatment of secondary hyperparathyroidism can have severe consequences, such as hyperplastic parathyroid glands, renal osteodystrophy and cardiovascular diseases.

Paricalcitol (Zemplar®) is a recently introduced third generation vitamin D analogon.

Paricalcitol is supposed to have several advantages in comparison to the “old” vitamin D alfacalcidol (Etalpha®).
According to several trials, paricalcitol corrects parathormone (PTH) levels faster and reduces the incidences of hypercalcemia. Trials and evidence are limited, so the question if paricalcitol is more effective than the “old” vitamin D analoga alfacalcidol and calcitriol remains relevant. This trial compares paricalcitol with alfacalcidol, the most frequently used vitamin D in the Netherlands. Treatment with paricalcitol is four times more expensive that treatment with alfacalcidol. This trial compares effectiveness, safety and costs of paricalcitol and alfacalcidol. With this trial treatment of secondary hyperparathyroidism in hemodialysis patients can be optimized.

Study objective

Paricalcitol induces a more effective reduction of the PTH level than alfacalcidol in hemodialysis pa-tients with secondary hyperparathyroidism

NL
Paricalcitol geeft een effectievere daling van de PTH spiegel ten opzichte van alfacalcidol bij hemodi-alysepatiënten met secundaire hyperparathyreoïdie.

Study design

- PTH:

Baseline, every 4 weeks

- Ca 2+ tot:
Baseline, every 2 weeks

- Ca2+ ion:
Baseline, every 2 weeks

- Albumin:
Baseline, every 2 weeks

- P:
Baseline, every 2 weeks

- Ca x P:
Baseline, every 2 weeks

- 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

Hemodialysis patients will be randomized.
Group A gets treated with alfacalcidol and Group B with paricalcitol.
After six months the groups switch.

Contacts

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Eligibility criteria

Inclusion criteria

1. Hemodialysis patients older than 18 years

2. Secondary hyperparathyroidism

Exclusion criteria

1. Severe hypercalcemia (Ca2+ >2,65 mmol/L)

2. Severe liver failure

3. Digoxin overdose

4. Hypersensitivity 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:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-08-2008
Enrollment:	114
Type:	Anticipated

Ethics review

Positive opinion

Date:	25-06-2008
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 31628
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL1309
NTR-old	NTR1358
CCMO	NL15946.029.07
ISRCTN	ISRCTN wordt niet meer aangevraagd
OMON	NL-OMON31628

Study results

Summary results
N/A