

The (cost)effectiveness of paricalcitol in the treatment of secondary hyperparathyroidism in hemodialysis patients.

Published: 19-05-2008

Last updated: 19-03-2025

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Parathyroid gland disorders
Study type	Interventional

Summary

ID

NL-OMON31628

Source

ToetsingOnline

Brief title

CEPS

Condition

- Parathyroid gland disorders
- Nephropathies

Synonym

hyperparathyroidism; increased activity of the parathyroids

Research involving

Human

Sponsors and support

Primary sponsor: Sint Lucas Andreas Ziekenhuis

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

Intervention

Keyword: chronic renal disease, paricalcitol, secondary hyperparathyroidism, vitamin D

Outcome measures

Primary outcome

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Secondary outcome

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Study description

Background summary

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Study objective

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Study design

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Intervention

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Study burden and risks

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Contacts

Public

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- Hemodialysis patient > 18 years
- Secondary hyperparathyroidism

Exclusion criteria

- Severe hypercalcemia ($\text{Ca}^{2+} > 2,65 \text{ mmol/L}$)
- Severe hepatic dysfunction
- Overdosage of digoxin
- Hypersensitivity to vitamine D or an overdosage of vitamin D
- Parathyroidectomy
- < 18 years
- Pregnancy
- Mental illness

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	14-07-2008
Enrollment:	114
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Etalpa
Generic name:	Alfacalcidol
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Zemplar
Generic name:	Paricalcitol
Registration:	Yes - NL intended use

Ethics review

Approved WMO	
Date:	19-05-2008
Application type:	First submission

Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	13-06-2008
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 24070
Source: NTR
Title:

In other registers

Register	ID
EudraCT	EUCTR2007-006645-41-NL
CCMO	NL15946.029.07
OMON	NL-OMON24070