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

.

Secondary outcome

.

Study description

Background summary

.

Study objective

.

Study design

.

Intervention

.

Study burden and risks

.

Contacts

Public
Sint Lucas Andreas Ziekenhuis

Jan Tooropstraat 164
1061AE Amsterdam
NL
Scientific
Sint Lucas Andreas Ziekenhuis

Jan Tooropstraat 164
1061AE Amsterdam
NL

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 hyperparathyoidism

Exclusion criteria

- Severe hypercalcemia (Ca2+ > 2,65 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:	Etalpha
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: Nationaal Trial Register
Title:

In other registers

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