Oral Paricalcitol versus Calcitriol in Peritoneal Dialysis Patients: effects on peritoneal transport and peritoneal defence

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In this pilot study, we are setting on to investigate the differential effects of the VDR activator paricalcitol versus calcitriol on peritoneal transport, peritoneal inflammation and peritoneal defense parameters in PD patients.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON37926

Source
ToetsingOnline

Brief title
Paricalcitol in PD

Condition

- Other condition

Synonym
Peritoneal damage due to peritoneal dialysis

Health condition

Verstoring peritoneale homeostase door peritoneaaldialyse

Research involving

Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: unrestricted grants;in het verleden gedaan door diverse farmaceutische bedrijven

Intervention

Keyword: Mesothelial cells, Mononuclear cells, Paricalcitol, Peritoneal dialysis

Outcome measures

Primary outcome

Endpoints are differences (25% or more) in markers of inflammation and

peritoneal transport between the paricalcitol and alphacalcidol groups.

Secondary outcome

None

Study description

Background summary

Because of survival benefit, vitamine D receptor activators (VDR) are routinely prescribed to (peritoneal) dialysis patients. Peritoneal dialysis has a poor technique survival, due ultrafiltration failure and peritoneal infections. In all causes of technique failure, the bioincompatible composition of PD-fluids is considered to be involved. Both neoangiogenesis, impaired wound healing by mesothelial cells, and hampered peritoneal defence of monocytes are intermediates between dialysis fluid administration and technique failure. Vitamine D has pleitropic effects, a.o. on cell division and maturation. However, these effects differ among the available vitamin D formulations. Therefore, it is interesting to evaluate differences in pleiotropic effects of the (standard) VDR calcitrioland a new VDR paricalcitol.

Study objective

In this pilot study, we are setting on to investigate the differential effects of the VDR activator paricalcitol versus calcitriol on peritoneal transport,

peritoneal inflammation and peritoneal defense parameters in PD patients.

Study design

Multicenter open-label randomized trial in patients on peritoneal dialysis. Following informed consent active vitamin D treatment will be stopped for a wash out period of 6 weeks. Patients using high calcium containing dialysis fluids (1.75 mmol/l) or low pH fluids (about 5 * 5.5.) are switched low Ca (1.25 mmol/l) and neutral pH fluids (Balance, Ca 1.25 mmol/l or Physioneal). During the study, Extraneal is only allowed in case of severe ultrafiltration problems (UF < 1000 ml/24h with 4 3.86%/4.25% glucose containing exchanges). Thereafter, the patients are randomized (stratified per centrum) according to patient number to receive a single-dose paricalcitol capsule of 1 ug or 1 tablet of calcitriol 0.25 ug. Dosage of study medication will be titrated towards PTH levels between 15 and 30 pmol/l according the KDOQI guidelines.

Intervention

Calcitriol or paricalcitol after a wash-out period (see study design).

Study burden and risks

Hypocalciemia during the washout period, due to the interruption of VDR therapy. Mild hypercalciemia after the start of VDR therapy.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

· the patient must provide written consent prior to starting the study
· patients must be over 18 years of age
· patients must have CKD stage 5 and treatment with peritoneal dialysis
· indication for active vitamin D therapy based on prevailing guidelines (after 6 weeks of wash-out)
· Calcium, corrected to albumen, < 2.6 mmol/l (after 6 weeks of wash-out)
· Not expected to receive a living donor transplant < 6 months

Exclusion criteria

· Patients who do not meet the specific inclusion criteria.
· UF < 1000 ml/24h with 4 3.86%/4.25% glucose exchanges or impossibility to stop Extraneal

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	25-05-2011
Enrollment:	24
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Rocaltrol
Generic name:	Calcitriol
Registration:	Yes - NL outside intended use
Product type:	Medicine
Brand name:	Zemplar
Generic name:	Paricalcitol
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	14-03-2011
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	22-08-2011
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-02-2012
Application type:	Amendment
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

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2007-004680-21-NL
CCMO	NL19381.029.10