Vascular calcification, vitamin K, phosphate binders and MGP

No registrations found.

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

Summary

ID

NL-OMON26614

Source
Nationaal Trial Register

Brief title
Vascular calcification, vitamin K, phosphate binders and MGP

Health condition

Vascular calcification, phosphate binders, chronic kidney disease, vitamin K, MGP

Sponsors and support

Primary sponsor: VUmc Amsterdam
Source(s) of monetary or material Support: Nederlandse nierstichting
Shire only study medication support, no financial support

Intervention

Outcome measures

Primary outcome

Absolute difference between serum level of dp-ucMGP and PIVKA II at week 8 between phosphate binder groups (between group analysis).

Secondary outcome

Absolute change from baseline to end of treatment period for lanthanumcarbonate group and calciumcarbonate group, respectively (longitudinal within group analysis). Association between change in dp-ucMGP and PIVKA II. Change in dp-ucMGP between week 16 and 20.

Study description

Background summary

Vascular calcification (VC) is a problem in patients with chronic kidney disease especially in end stage kidney disease. VC is associated with increased mortality. In recent literature there is vascular calcification which progresses with use of phosphate binders. There are some small studies which have shown that phosphate binders can bind vitamin K as well. Vitamin K is necessary in the vessel wall to counteract VC. In this trial we are taking a better look at this interaction, because if phosphate binders bind vitamin K this can cause VC.

Study objective

This research will have as aim to look at progression or decrease in vascular calcification in dialysis population with use different phosphate binders. There is a possibility that different binders bind vitamin K in a different way in intestinal tract and thereby cause different level of calcification. Better insight in mechanisms of vascular calcification under circumstance can lead to therapeutic options which inhibit calcification and benefit survival of dialysis patients.

Study design

start: start with one of the phosphate binders

8 weeks: change of phosphate binder

16 weeks: start vitamin K2 supplemantation

20 weeks: end of trial

Intervention

treatment with calciumcarbonate or lanthanum carbonate with supplemantation of vitamin K

Contacts

Public
Vumc Amsterdam

A. Neradova
Amsterdam
The Netherlands
020-4441123
Scientific
Vumc Amsterdam

A. Neradova
Amsterdam
The Netherlands
020-4441123

Eligibility criteria

Inclusion criteria

Haemodialysis patients aged 18 years or above without the prospect of renal function recovery, planned renal transplantation, and life expectancy longer than six months.

Exclusion criteria

1 Use of vitamin K antagonists

2 Calcium under 2,1 mmol/l or above 2,6 mmol/l, after correction for albumin level

3 Pregnancy

4 Baseline phosphate under 1,4 mmol/l

5 Allergy or intolerance for study medication

6 PTH <15 or >65 pmol/l

Study design

Design

Study type: Interventional

Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-11-2014
Enrollment:	16
Type:	Anticipated

Ethics review

Positive opinion

Date:	09-12-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 44005
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4902
NTR-old	NTR5004
CCMO	NL36810.094.13
OMON	NL-OMON44005

Study results

Summary results

1 Arterial media calcification in end stage renal disease: impact on all cause and cardiovascular mortality. London GM, Guerin AP, Marchais S.J, et al. Nephrol Dial Transplant. 2003 Sept; 18(9): 1731-40.
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14 Krueger T, Westenfeld R, Ketteler M, Schurgers LJ, Floege J. Vitamin K deficiency in CKD patients, a modifiable risk factor for vascular calcification. Kidney International 2009; 76: 18–22.
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16 Koos R, Mahnken AH, Muhlenbruch G, et al. Relation of oral anticoagulation to cardiac valvular and coronary calcium assessed by multislice spiral computed tomography. Am J Cardiol 2005; 96: 747-749.
17 Takagi K, Masuda K, Yamazaki M, et al. Metal and ion and vitamin adsorption profiles of phosphate binder ion-exchange resins. Clin. Nephrol. 2010 Jan; 73(1): 30-5.

18 Sevelamer Summary Product information.
19 Pierce D, Hossack S, Poole L, et al.The effect of sevelamer carbonate and lanthanum carbonate on the pharmacokinetics of oral calcitriol.Nephrol. Dial. Transplant. 2011 May; 26(5): 1615-21.
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