Vascular calcification, vitamin K, phosphate binders and MGP

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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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26614

Bron
Nationaal Trial Register

Verkorte titel
Vascular calcification, vitamin K, phosphate binders and MGP

Aandoening

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

Ondersteuning

Primaire sponsor: VUmc Amsterdam
Overige ondersteuning: Nederlandse nierstichting
Shire only study medication support, no financial support

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Absolute difference between serum level of dp-ucMGP and PIVKA II at week 8 between

phosphate binder groups (between group analysis).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

treatment with calciumcarbonate or lanthanum carbonate with supplemantation of vitamin K

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	03-11-2014
Aantal proefpersonen:	16
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	09-12-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 44005
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4902

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

Resultaten

Samenvatting resultaten

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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