Patient preference based phosphate binder therapy

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Patient preference-based phosphate binding therapy will improve patient’s satisfaction with the treatment leading to higher adherence and subsequently to an improved serum phosphate control. In this pilot study we will test the feasibility of a…

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON25073

Bron
Nationaal Trial Register

Verkorte titel
Triple-P

Aandoening

Chronic Kidney Disease, end-stage renal disease

Ondersteuning

Primaire sponsor: Amsterdam UMC, location VUmc
Overige ondersteuning: Dutch Kidney Foundation

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Patient satisfaction with phosphate treatment measured with the Treatment Satisfaction Questionnaire for Medication (TSQM, version II).

Toelichting onderzoek

Achtergrond van het onderzoek

Hyperphosphatemia is associated with increased mortality and (cardiovascular) morbidity, especially in patients on dialysis. In addition to dietary interventions and optimization of dialysis schemes, most dialysis patients also require phosphate binding medication. However, a substantial proportion of these patients do not attain adequate phosphate control due to non-adherence. Importantly, there are no firm scientific data that dictate which phosphate binder should be used as first line intervention with the possible exception of higher doses of calcium containing phosphate binders, which are associated with a higher mortality risk. The most effective therapy might be the therapy that best fits the preferences of the individual patient, i.e. the binder that is best tolerated and is the easiest to use in daily routine of an individual patient. In this pilot study we will test the feasibility of a strategy in which patient preference, after a short exposure to treatment options, determines the choice for a specific phosphate binder and whether this improves patient satisfaction with treatment and subsequently leads to higher adherence and improved phosphate control.

Doel van het onderzoek

Patient preference-based phosphate binding therapy will improve patient’s satisfaction with the treatment leading to higher adherence and subsequently to an improved serum phosphate control. In this pilot study we will test the feasibility of a strategy in which patient preference, after a short exposure to treatment options, determines the choice for a specific phosphate binder.

Onderzoeksopzet

Baseline measurement will be followed by a 2 weeks wash-out period. The intervention periods consists of 22 weeks (6 weeks trial periods (3*2 wks), 10 weeks up titration and 4 weeks trial efficacy phase.

Onderzoeksproduct en/of interventie

Patients will use three different phosphate lowering agents consecutively in random order for 2 weeks per treatment: sevelamer, lanthanumcarbonate and sucroferric oxyhydroxide. After these trial periods the patient will choose their initial treatment followed by a period of 10 weeks in which treatment will be up titrated to reach the phosphate goal (i.e. <1.8 mmol/L). End points will be measured after a final 4 weeks “trial efficacy phase”.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Age ≥ 18 years
- Haemodialysis patients (since at least 3 months)
- Necessity of phosphate binding therapy
- Written informed consent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Intolerance to one of three types of phosphate binders
- Expected cessation of dialysis treatment within 6 months

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd

Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-04-2020
Aantal proefpersonen:	40
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8400
Ander register	METc VUmc : pending

Resultaten