Patient preference based phosphate binder therapy

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25073

Source
Nationaal Trial Register

Brief title
Triple-P

Health condition

Chronic Kidney Disease, end-stage renal disease

Sponsors and support

Primary sponsor: Amsterdam UMC, location VUmc
Source(s) of monetary or material Support: Dutch Kidney Foundation

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Quality of life (SF-12), dialysis symptoms index (DSI), number of treatment switches, plasma phosphate , drug side effects questionnaire, drug adherence, serum PTH and Alkaline phosphatase.

Study description

Background summary

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.

Study objective

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.

Study design

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.

Intervention

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”.

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2020
Enrollment:	40
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL8400
Other	METc VUmc : pending

Study results