A combined, tailored pharmacist intervention with dose optimization of phosphate binding drugs to improve phosphate control in patients on dialysis.

No registrations found.

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

Summary

ID

NL-OMON24286

Source
NTR

Brief title
PIDO-P

Health condition

Chronic kidney disease, end-stage renal disease, hemodialysis, hyperphosphatemia

Sponsors and support

Primary sponsor: Franciscus Gasthuis and Vlietland
Source(s) of monetary or material Support: Franciscus Gasthuis and Vlietland, possibly cofunding via Pionier+ program, Nierstichting

Intervention

Outcome measures

Primary outcome

The primary outcome variable is the difference between the mean serum phosphate level over the 3 months before the intervention, and the mean serum phosphate level over the first 3 months after the intervention.

Secondary outcome

• the percentage of patients with a mean serum phosphate level of 1.5 mmol/L or lower, measured the 3 months before and 3, 6 and 12 months after the intervention.
• the trend in serum phosphate level during follow-up
• the difference between the mean serum phosphate level over the 3 months before the intervention, and the serum phosphate level at 6 and 12 months after the intervention
• the implementation fidelity of the intervention, including barriers and facilitators for implementation
• pharmaceutical literacy
• medication adherence (MARS-5) before and after the intervention

Study description

Background summary

In this study we will investigate if a combined, tailored pharmacist intervention including dose optimization will improve phosphate control in hemodialysis patients. We hypothesize that a reduction in phosphate binder pill burden in combination with a combined tailored intervention, taking into account patient preferences, will lead to lower serum phosphate levels, by increasing treatment adherence.

This combined, tailored intervention consists of three visits with patient counselling and two follow-up visits without counselling. In the first visit we will investigate medication adherence, pharmaceutical literacy and patient barriers for the correct use of phosphate binding drugs. We will use several questionnaires (MARS-5: medication adherence rating scale-5, QBS: Quick Barrier Scan, RALPH: Recognizing and Addressing Limited Pharmaceutical literacy). Based on these questionnaires we will select one or more modules of the Tailored Information Guide (TIG).

This Tailored Information Guide consists of five intervention modules (IM): IM1 regards knowledge/information, IM2 addresses forgetfulness, IM3 addresses side effects, IM4 addresses practical problems, and IM5 addresses negative beliefs. The TIG provides an overview of intervention recommendations that pharmacists should use to inform and advise participants to overcome the identified barriers. Information should be provided about hyperphosphatemia, and the use of and need for phosphate binders. Moreover, participants' representations of hyperphosphatemia and its treatment should be discussed. Interventions recommendations, for instance, include changing medication regime in accordance with the nephrologist, using intake-supporting tools (pill box, medication alarm), registering for pharmacy intake-supporting services or discussing negative medication-related beliefs with

the pharmacist.

During the second visit, one to two weeks after the first visit, patient preferences regarding the use of phosphate binding drugs will be discussed, as well as the selected TIG modules. Meanwhile a dose reduction will be carried out, according to a predefined algorithm. Based on all this, a tailored plan will be made using shared-decision making. This plan will be written down and given to the patient and communicated to the treating nephrologist.

The third visit will take place approximately three months after the first visit. During this visit the pharmacist will discuss the patient's experiences with the treatment plan. If necessary the plan will be adjusted. The MARS-5 will be used to evaluate medication adherence at the end of the intervention.

During the first three visits, patients' phosphate levels will be managed by the pharmacist. After the third intervention, patients will be returned to usual care.

The fourth and fifth visit will take place approximately six and twelve months after start of the intervention, during which phosphate levels and dose of phosphate binding drugs will be evaluated.

To study the implementation of the intervention, we will also evaluate the implementation fidelity of the intervention. Quantitative and qualitative data will be collected and analysed according to Carrolls' Conceptual Framework for Implementation Fidelity.

Study objective

We hypothesize that a reduction in phosphate binder pill burden in combination with a combined tailored intervention, taking into account patient preferences, will lead to lower serum phosphate levels, by increasing treatment adherence.

Study design

3 months before and 3, 6 and 12 months after the intervention

Intervention

The intervention is a dose reduction of phosphate binding therapy in combination with personalized pharmacist-led counselling.

Contacts

Public
Franciscus Gasthuis and Vlietland
Francisca Johanna van den Oever

0031104616510
Scientific
Franciscus Gasthuis and Vlietland
Francisca Johanna van den Oever

0031104616510

Eligibility criteria

Inclusion criteria

- Both the mean serum phosphate level over the last 3 months and the last serum phosphate level are higher than 1.5 mmol/L.
- Prescription for 6 or more phosphate binder units daily
- Age of 18 years or older
- Medication dispensed by Poli-apotheek Franciscus Gasthuis
- Intermittent hemodialysis for at least 3 months preceding the inclusion date.
- Hemodialysis during entire follow-up
- Sufficient language proficiency to comprehend instructions concerning study procedures, such as informed consent.

Exclusion criteria

- Patients residing in a nursing home
- Cognitive impairment, resulting in failure to comprehend instructions concerning study procedures.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2021
Enrollment:	45
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	15-08-2021
Application type:	First submission

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	NL9650
Other	MEC-U : W21.142

Study results