Phosphate Reduction Or Supplementation Intervention Trial

No registrations found.

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

Summary

ID

NL-OMON27814

Source
NTR

Brief title
PROSIT

Health condition

Chronic Kidney Disease (chronische nierinsufficiëntie)

Sponsors and support

Primary sponsor: University Medical Center Groningen
Source(s) of monetary or material Support: The Netherlands Organisation for Health Research and Development (ZonMW)

Intervention

Outcome measures

Primary outcome

Residual albuminuria (24h urine collection)

Secondary outcome

C-terminal FGF23 levels, 24-hourly phosphorus excretion, serum phosphate levels, serum calcium levels, 24-hourly calcium excretion, residual proteinuria, systolic blood pressure, Serum calcification propensity

Study description

Background summary

Chronic Kidney Disease (CKD) is an important global health issue, affecting ~10% of the world population. Despite current state-of-the-art treatment, mainly pharmacological inhibition of the renin-angiotensin-aldosterone system (RAAS), renal function loss remains progressive in many patients. Recent observational studies suggest that factors involved in mineral metabolism, and the phosphaturic hormone fibroblast growth factor 23 (FGF23) in particular, may influence the renoprotective efficacy of RAAS-blockade. Circulating FGF23 levels increase in parallel with renal function loss and high levels of FGF23 are strongly associated with morbidity and mortality in patients with CKD. FGF23 levels can be reduced by limiting the intestinal uptake of phosphate. Based on these findings, we hypothesise that reducing phosphate intake in CKD patients could be an effective strategy to improve the response to RAAS-blockade. To test this hypothesis, we will conduct a randomised controlled, double blinded, cross-over intervention study.

Study objective

Modulation of phosphate intake can affect the antiproteinuric efficacy of RAAS-blockade therapy in CKD patients

Study design

week 3 and 6 of each study period (cross-over)

Intervention

Low phosphate diet combined with phosphate supplement or placebo

Contacts

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Eligibility criteria

Inclusion criteria

• CKD

• Estimated GFR >30 mL /min/1.73 m2

• Residual albuminuria ≥ 500 mg /day despite treatment with optimally dosed ACEi or ARB.

• Age ≥ 18 years

Exclusion criteria

• Current use of phosphate binder therapy

• Hyperphosphatemia >2.00 mmol/L

• Hypocalcaemia (corrected serum calcium <2.00 mmol/L)

• Hypercalcaemia (corrected serum calcium >2.60 mmol/L)

• Hyperkalemia (serum potassium >5.50 mmol/L)

• Blood pressure >180/100 mmHg after study run-in period.

• Chronic diarrhea (>5 diarrhea stools/day for >2 weeks

• Chronic inflammatory bowel disease

• Chronic NSAID use

• Diabetes Mellitus

• Non-glomerular source of proteinuria

• Contraindications to ACEi therapy or high/low phosphate intake

• Unstable disease (at the discretion of the nephrologist, such as persistent renal function loss > 6 mL/min/1.73m2 per year, not explainable by intercurrent events, with accompanying changes in serum creatinine and urea).

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	01-01-2016
Enrollment:	42
Type:	Unknown

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	NL5443
NTR-old	NTR5570
Other	UMCG : 201500492

Study results

Summary results
N/A