THE EFFECT OF NIACINAMIDE SUPPLEMENTATION ON PHOSPHATE CONCENTATIONS IN DIALYSIS PATIENTS.

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Ethical review	Approved WMO
Status	Pending
Health condition type	Bone, calcium, magnesium and phosphorus metabolism disorders
Study type	Interventional

Summary

ID

NL-OMON41924

Source
ToetsingOnline

Brief title
the DiaNia-study

Condition

- Bone, calcium, magnesium and phosphorus metabolism disorders
- Renal disorders (excl nephropathies)

Synonym
high phosphate level, hyperphospatemia

Research involving
Human

Sponsors and support

Primary sponsor: Ziekenhuis Gelderse Vallei
Source(s) of monetary or material Support: Ziekenhuis Gelderse Vallei (subsidie)

Intervention

Keyword: dialysis, Niacinamide, phosphate

Outcome measures

Primary outcome

The main study parameter is the serum phosphate concentrations in week 8 and

12.

Secondary outcome

Other study parameters are compliance to phosphate binders and

supplement-related complaints such as nausea, diarrhea, flushing and itchiness

that leads to dropout.

Study description

Background summary

Despite the repeatedly demonstrated beneficial effect of niacin and its analogue niacinamide (=nicotinamide) on serum phosphate concentrations, this has not resulted in their incorporation in (inter)national guidelines. We previously carried out a pilot study in dialysis patients (not published) which confirmed the effect on serum phosphate concentrations but also showed that niacin was badly tolerated by most patients. We suspect that this is the reason why niacin treatment has not been implemented in the clinic. After we established in some patients that niacinamide was tolerated much better than niacin, we decided to study now with niacinamide, more patients, and a better study design.

Study objective

The main study parameter is the routine measurement of serum phosphate concentrations after 8 and 12 weeks. Other study parameters are compliance to phosphate binders and supplement-related complaints such as nausea, diarrhoea, flushing and itchness that leads to dropouts .

Study design

Randomized, crossover study with niacinamide or placebo for 12 weeks followed by the alternate intervention for another 12 weeks.
Patients will receive niacinamide or placebo, containing only the carrier material The patients will receive 1 dose of 250 mg or 1 placebo tablet in the first 4 weeks, and 2 doses of 250 mg or 2 doses placebotablets in the last 8 weeks.

Intervention

During 12 weeks intake of daily niacinamide followed by placebo daily during 12 weeks or reverse.

Study burden and risks

Niacinamide has a Tolerable Upper Intake Limit (UL) of 900 mg/d (EFSA). This value has a substantial margin of safety built in to identify this UL as a value well below the clinical trial values that showed no adverse effects. Patients who benefit (in terms of decreased serum phosphate concentrations) will be advised to continue taking the supplements.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Hemodialysis patients
- Adults (* 18 year)
- Stable dialysis state (at least 6 months hemodialysis) as measured at baseline

Exclusion criteria

- Severely malnourished patients as diagnosed by the dietitian
- Patients who dialyse at night in-hospital
- Language barrier

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-07-2015
Enrollment:	30
Type:	Anticipated

Ethics review

Approved WMO Date:	20-06-2016
Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)

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
CCMO	NL50499.081.14