phosphorus intake and FGF23 blood levels

Published: 11-08-2008
Last updated: 06-05-2024

Objective of this study is to study the influence of phosphate intake on FGF23 blood levels, in order to understand kinetics of FGF23 in relation to phosphate intake.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON31826

Source
ToetsingOnline

Brief title
phosphorus intake and FGF23 blood levels

Condition

- Other condition

Synonym
niet van toepassing

Health condition

het gaat om gezonde proefpersonen

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Fibroblast Growth Factor 23, Phosphate intake, PTH, Vitamin D

Outcome measures

Primary outcome

FGF23 serum concentration, during the period of phosphate restriction and the

period of high phosphate intake.

Secondary outcome

not applicable

Study description

Background summary

Fibroblast Growth Factor 23 (FGF23) is a relatively unknown protein which is involved in phosphatemetabolism. It is known that FGF23 serum concentration is elevated in patients suffering from chronical kidney disease (CKD). This elevation of FGF23 serum concentration seems to be associated with hyperphosphotemia existing in these patients. In the future FGF23 might be an important marker to diagnose latently present hyperphosphatemia early in CKD, in order to start treatment with phosphate binders at an earlier stage. This might be associated with a slower decline of renal function in these patients, and/or early ameliorate 1,25 dihydroxycholecalciferol deficiency, since FGF23 inhibits 1alpha-hydroxylase.

Study objective

Objective of this study is to study the influence of phosphate intake on FGF23 blood levels, in order to understand kinetics of FGF23 in relation to phosphate intake.

Study design

On day 1 there will be a baseline examination of FGF23 serum concentration during the day as well as creatinine, calcium, phosphate and PTH, urea, albumin, 25(OH)vitamin D3 and 1.25(OH)2 vitamin D3. The blood samples will be taken in the morning (fasting) (T= 0), before lunch (T=4) and before dinner (T=8). Breakfast and lunch are as usual, dinner has to be phosphate restricted

on day 1. After the first blood collection of day 1, the 24h- urine collection starts. The collected urine will be examined on natrium, kalium, calcium, phosphate, creatinine, urea and total protein excretion.
On day 2 the diet is phosphate restricted. This day another three blood samples are taken: T=0 (fasting, before phosphate restricted breakfast), T= 4 (before phosphate restricted lunch) and T= 8 (before phosphate restricted dinner).
After the first blood collection of day 2, the 24h- urine collection starts.
The blood samples will be examined as described above.
In the morning of day 3 there shall be another blood collection and the collected urine will be examined as described above.
Day 4 until day 7 the diet is as usual.
On day 8 until day 10 the same procedure is repeated; the only difference is that the phosphate intake will be high this time.

Study burden and risks

the test person has be compliant to a diet during two times one and a half day, he has to collect his urine for four days and a total amount of 14 bloodsamples will be taken.

Contacts

Public
Vrije Universiteit Medisch Centrum

postbus 7057
1007 MB Amsterdam
Nederland
Scientific
Vrije Universiteit Medisch Centrum

postbus 7057
1007 MB Amsterdam
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

healthy adults (> 18 years)

Exclusion criteria

smoking, pregnancy and a serum creatinine level > 100 micromol/liter

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-08-2008
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	11-08-2008
Application type:	First submission

Review commission: METC Amsterdam UMC

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	NL23674.029.08