

Hormonal changes induced by changing amounts of protein and phosphorus in the diet of healthy volunteers

Submission date 06/05/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 27/05/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 30/08/2011	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
2008/155

Study information

Scientific Title
Effects of changes in dietary phosphorus intake on fibroblast growth factor 23 (FGF23) levels in healthy volunteers: a controlled crossover trial

Study objectives

Background:

This study is related to patients with kidney disease. Kidney disease, as defined by a decline in estimated Glomerular Filtration Rate (GFR), as even in early stages related to disturbances in the metabolism of minerals, especially calcium and phosphorus, and Fibroblast growth factor 23 (FGF23). The latter is related to clinical endpoints and mortality.

Hypothesis

Changes in phosphate intake lead to parallel changes in levels of FGF23, even in healthy volunteers. These changes in FGF23 in turn lead to increases in phosphaturia and changes in levels of 1,25 dihydroxyvitamin D, both independent from possible changes in PTH or serum phosphate levels.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The local medical ethics committee (Medisch Ethische Toetsingscommissie) of Vrije University Medical Centre (VUMC) approved on the 11th of August 2008 (ref: 2008/155)

Study design

Non-randomised controlled crossover group trial

Primary study design

Interventional

Study type(s)

Other

Health condition(s) or problem(s) studied

Kidney disease

Interventions

Subjects are switched from regular diet to phosphate-restricted diet for two days, and the back to regular diet for ten days. After that they are switched from regular diet to phosphate-enriched diet and the back again. No other interventions are made.

Both the primary and secondary endpoint were determined during the interventional periods, because changes induced by the intervention are almost immediate.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Changes in FGF23 levels, determined using sandwich ELISA for both C-terminal FGF23 (provided by Immutopics, San Clemente, USA) and Intact FGF23 (provided by Kainos, Japan).

Key secondary outcome(s)

1. Changes in phosphaturia
 2. Changes in levels of metabolites of vitamin D (1,25 dihydroxyvitamin D)
- Outcomes analysed by standard laboratory techniques and radio-immuno assay (IDS, Tyne and Wear, UK) respectively

Completion date

31/12/2008

Eligibility

Key inclusion criteria

1. Male or female
2. Non-smoking subjects
3. Normal renal function, as defined by estimated Glomerular Filtration Rate (GFR) above 80 ml /min.
4. Females should have a negative test for pregnancy at baseline

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Abnormal kidney function
2. Substantial comorbidity

Date of first enrolment

01/08/2008

Date of final enrolment

31/12/2008

Locations

Countries of recruitment

Netherlands

Study participating centre

De Boelelaan 1117
Amsterdam
Netherlands
1081 HV

Sponsor information

Organisation

Vrije University Medical Centre (VUMC) (Netherlands)

ROR

<https://ror.org/00q6h8f30>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Vrije University Medical Centre (VUMC) (Netherlands) - Departments of nephrology and biochemistry

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration