ISRCTN10876564 https://doi.org/10.1186/ISRCTN10876564

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

Submission date	Recruitment status	[ ] Prospectively registered
06/05/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
27/05/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
30/08/2011	Urological and Genital Diseases	[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 committe (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

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details below to request a patient information sheet

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 phopsphate-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 measure
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).

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

Overall study start date
01/08/2008

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

Age group
Adult

Sex
Both

Target number of participants
10

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
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1081 HV

Sponsor information

Organisation
Vrije University Medical Centre (VUMC) (Netherlands)

Sponsor details
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Sponsor type
Hospital/treatment centre

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration