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A study of effective dietary therapy to control of hyperphosphatemia

Submission date
14/07/2015

Recruitment status
No longer recruiting

Registration date
06/10/2015

Overall study status
Completed

Last Edited
04/11/2015

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Phosphorus is an essential mineral that is required by every cell in the body for normal function, but high phosphorus levels can lead to cardiovascular (heart) disease. Shift workers have an increased risk of coronary heart disease, suggesting that eating at night may affect how the body uses phosphorus (phosphorus metabolism), but this has not been investigated. The purpose of this study was to investigate the effects of nocturnal eating on phosphorus metabolism.

Who can participate?
Healthy men aged 20-40.

What does the study involve?
Participants were served test meals three times a day (breakfast at 07:30, lunch at 12:30, dinner at either 17:30 or 22:30). Blood and urine samples were collected to assess phosphorus levels until the following morning.

What are the possible benefits and risks of participating?
Participants will find out their health status. There is a risk of side effects from the blood sample collection.

Where is the study run from?
University of Shizuoka (Japan).

When is the study starting and how long is it expected to run for?
July 2013 to January 2015.

Who is funding the study?
Ministry of Education, Culture, Sports, Science and Technology (Japan).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
University hospital Medical Information Network (UMIN)/UMIN000014380

Study information

Scientific Title
Effect of nocturnal eating on phosphorus excretion in young subjects: a randomized crossover trial

Study objectives
To assess the effects of nocturnal eating on phosphorus metabolism.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Ethics Committee of the University of Shizuoka, 25/06/2013, ref: University of Shizuoka 25-9

Primary study design
Interventional

Study design
interventional randomized crossover trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Hyperphosphatemia

Interventions

The subjects were served test meals three times a day (breakfast 07:30 h, lunch 12:30 h, dinner 17:30 or 22:30 h). Blood and urine samples were collected to assess diurnal variation until the following morning.

Intervention Type
Other

Primary outcome(s)
Serum phosphorus level, measured at baseline (0 hours) and 2.5, 5.0, 7.5, 10.0, 12.5, 15.0, 24.0 hours after

Key secondary outcome(s)
1. Urinary phosphorus excretion, measured at four times over the 24 hours: between 07:30 h to 12:30 h (morning); 12:30 h to 17:30 h (afternoon); 17:30 h to 22:30 h (evening); and 22:30 h to 07:30 h, the following morning (night)
2. Serum parathyroid hormone level, measured at baseline (0 hours) and 2.5, 5.0, 7.5, 10.0, 12.5, 15.0, 24.0 hours after
3. Serum FGF23 level, measured at baseline (0 hours) and 2.5, 5.0, 7.5, 10.0, 12.5, 15.0, 24.0 hours after

Completion date
08/01/2015

Eligibility

Key inclusion criteria
1. 20-40 years old
2. Male

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Sex
Male

Key exclusion criteria
1. Smoking
2. History or medication use for glucose tolerance, renal or hepatic dysfunction

Date of first enrolment
13/07/2013

Date of final enrolment
31/10/2014

Locations

Countries of recruitment
Japan

Study participating centre
University of Shizuoka
Japan
422-8526

Sponsor information

Organisation
University of Shizuoka (Japan)

ROR
https://ror.org/01w6wtk13

Funder(s)

Funder type
Government

Funder Name
Ministry of Education, Culture, Sports, Science and Technology (Japan)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	08/10/2015		Yes	No