A study of effective dietary therapy to control of hyperphosphatemia

Submission date 14/07/2015	Recruitment status No longer recruiting	 Prospectively registered Protocol
Registration date 06/10/2015	Overall study status Completed	
Last Edited 04/11/2015	Condition category Nutritional, Metabolic, Endocrine	 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? Dr Masae Sakuma sakuma@u-shizuoka-ken.ac.jp

Contact information

Type(s) Scientific

Contact name Dr Masae Sakuma

Contact details

52-1, Yada, Suruga-ku Shizuoka Japan 422-8526 +81 (0)54 264 5596 sakuma@u-shizuoka-ken.ac.jp

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers 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

Study design interventional randomized crossover trial

Primary study design Interventional

Secondary study design

Randomised cross over trial

Study setting(s) Other

Study type(s) Prevention

Participant information sheet

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 measure

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

Secondary outcome measures

 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)
 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
 Serum FGF23 level, measured at baseline (0 hours) and 2.5, 5.0, 7.5, 15.0, 24.0 hours after

Overall study start date

13/07/2013

Completion date 08/01/2015

Eligibility

Key inclusion criteria

1. 20-40 years old 2. Male

Participant type(s)

Healthy volunteer

Age group

Adult

Sex Male

Target number of participants 14

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)

Sponsor details 52-1, Yada, Suruga-ku Shizuoka Japan 422-8526

Sponsor type University/education

ROR https://ror.org/01w6wtk13

Funder(s)

Funder type Government

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

Results and Publications

Publication and dissemination plan To be confirmed at a later date

Intention to publish date

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