

# A study of effective dietary therapy to control of hyperphosphatemia

<b>Submission date</b> 14/07/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 06/10/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 04/11/2015	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> 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**

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

**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?
<a href="#">Results article</a>	results	08/10/2015		Yes	No