ISRCTN74325268 https://doi.org/10.1186/ISRCTN74325268

Calcium supplementation on blood glucose, lipids and obesity in Chinese women

Submission date	Recruitment status	[ ] Prospectively registered
14/09/2011	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
07/10/2011	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
30/11/2012	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims:
In the last 20 years, in China, calcium supplementation is common and is recommended for postmenopausal women to prevent osteoporosis and improve health. However, until now, there have not been any systematic studies to show the effect of calcium supplements on Chinese womens health. The aim of this study is to investigate the effect of calcium supplementation on blood glucose, fat levels and obesity in Chinese women.

Who can participate?
Females aged 30 - 60 years with a stable body weight during 6 months before the study.

What does the study involve?
Participants were first sorted by age and then randomly allocated into two groups (calcium supplements group and controlled group). The subjects in the calcium supplements group received a calcium tablet each day to take after supper. Those in the other group took a dummy tablet each day, which looked like the calcium tablet, but did not contain any calcium. This was also to be taken after supper. At the end of the study, participants were asked to provide blood samples to see if these tablets had an effect on the participants metabolism on their body and the effect on other body functions.

What are the possible benefits and risks of participating?
Those who received the calcium supplements may be at a lower risk of osteoporosis. There may be bruising and discomfort at the site of the blood test as with any blood test. However, the amounts of blood we took were small enough that they should not cause anaemia or make the subjects feel fatigue.

Where is the study run from?
Department of Nutrition and Food Hygiene, Harbin Medical University.

When is the study starting and how long is it expected to run for?
The study started in December 2008 and ended in December 2009.

Who is funding the study?
Danone Institute China - Diet Nutrition Research and Communication Grant ref: DIC2008-05

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Effect of calcium supplementation on blood glucose, lipids and obesity in Chinese women: a double-blind, placebo-controlled trial

Study objectives
A number of studies of calcium supplements on prevention of osteoporosis, weight reduction, improvements in blood glucose and lipids profiles have been researched in the past several decades. However, no definite conclusion was obtained on the effects of calcium supplements on human health. In China, calcium supplementation is prevalent and especially recommended for postmenopausal women to prevent osteoporosis and improve health for the last 20 years. No systematic conclusion of calcium supplements on Chinese womens health has been obtained so far. We therefore carried out this project to evaluate calcium supplementation on blood glucose, lipids and obesity in Chinese women.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethical Committee of Public Health College, Harbin Medical University approved on 20 November 2008 (ref: 2008013)

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Screening

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

Health condition(s) or problem(s) studied
Obesity, blood glucose and lipids

Interventions
Eligible subjects were first sorted by age and then randomized into two groups with a block size of 2, with random numbers generated by statistical software SPSS.

The subjects in the calcium supplements group received a 1500mg calcium carbonate tablet (containing 600mg calcium) 30 minutes after supper once daily.

The subjects in placebo group took a placebo tablet (starch) instead of calcium carbonate at the same times and amounts as in the intervention group. The intervention lasted for 1 year.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Calcium carbonate

Primary outcome measure

1. The effects of calcium supplementation on glucose metabolism: fasting glucose and insulin, 2-hour post prandial glucose, Homeostasis Model of Assessment - Insulin Resistance (HOMA-IR) and glycated hemoglobin (HbA1c) (%)
2. The effects of calcium supplementation on lipids metabolism:
2.1. Serum cholesterol, Triglyceride, HDL cholesterol (HDL-C), low-density-lipoprotein cholesterol (LDL-C), apolipoprotein A-I (Apo A-I) and Apolipoprotein B (Apo B)
2.2. Serum lipoprotein lipase (LPL) and adipocyte fatty acid-binding protein (AFABP)
2.3. Serum free fatty acid (FFA) profile
3. The effect on obesity: anthropometric indexes
4. Serum calcium relative indexes, including parathyroid hormone (PTH), 1.25-hydroxyvitamin D3, serum calcium, thyrocalcitonin and serum phosphate

Secondary outcome measures
1. Baseline characteristics: age, gender, body mass index (BMI), blood pressure and physical activity level
2. Daily intake of nutrients by the subjects at baseline and after 1 year intervention
3. Blood biochemistry characteristics of the subjects at baseline and after 1-year intervention: red blood cell, white blood cell, hemoglobin, total protein, albumin, urea nitrogen, creatinine, alanine transaminase and aspartate transaminase

Overall study start date
16/12/2008

Completion date
15/12/2009

Eligibility

Key inclusion criteria
1. Aged 30-60 years, healthy female
2. Stable body weight during 6 months before the study

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
Recruited 400

Key exclusion criteria
1. A history of cerebrovascular, cardiovascular, renal, hepatic, diabetes, or other medical diseases likely to interfere with the study
2. Taking medications, which were likely to interfere with the study
3. Received calcium supplements at least for one year before the beginning of the study

4. Pregnant or breast-feeding
5. Information incompleted or unwillingness to attempt to comply with the intervention

Date of first enrolment
16/12/2008

Date of final enrolment
15/12/2009

Locations

Countries of recruitment
China

Study participating centre
157 Baojian Road
Harbin
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150081

Sponsor information

Organisation
Harbin Medical University (China)

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Sponsor type
University/education

Website
http://www.hrbmu.edu.cn/english/index.htm

ROR
https://ror.org/05jscf583

Funder(s)

Funder type
Research organisation

Funder Name
Danone Institute (China) - Diet Nutrition Research and Communication Grant (ref: DIC2008-05)

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