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Effect of calcium supplementation on iron bioavailability in women aged 35 to 45 years old

Submission date
03/06/2011

Recruitment status
No longer recruiting

Registration date
13/07/2011

Overall study status
Completed

Last Edited
23/05/2017

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
Iron is an essential nutrient involved in body processes such as red blood cell production and oxygen transport. Iron deficiency is a common nutritional disorder and the most common cause of anemia (a reduction in the number of red blood cells). Calcium is an essential mineral involved in growth. If the diet is not able to supply the body's requirements, supplementation or fortification is a cost-effective alternative. Interactions between nutrients may increase the risk of nutritional deficiencies. For example, calcium may interfere with the body's absorption of iron. The aim of this study is to determine the effect of calcium supplementation on iron absorption.

Who can participate?
Healthy women aged 35 to 45

What does the study involve?
Participants are randomly allocated to take three pills per day of either a calcium supplement or a placebo (dummy supplement). Blood samples are taken to measure the participants' iron levels before and after the supplementation. Weight, height and dietary calcium and iron intake are also measured.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
University of Chile (Chile)

When is the study starting and how long is it expected to run for?
June 2011 to August 2011

Who is funding the study?
Chilean Science Council (Chile)

Who is the main contact?
Prof. Fernando Pizarro
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A randomized controlled trial investigating the effect of calcium supplementation on iron bioavailability in women aged 35 to 45 years old in Santiago, Chile

Study objectives
1. Heme iron bioavailability decreases after 43 days of calcium supplementation
2. Non-heme iron bioavailability decreases after 43 days of calcium supplementation

Each participant was informed about the benefits, risks and reliability of the study through an informed consent. Participation was voluntary, remuneration was provided, and all subjects were free to withdraw at any stage of the study. Proceedings were done after reading and signed the written informed consent.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee at the Institute of Nutrition and Food Technology (INTA), University of Chile, 18/06/2008, ref: 13/200

Study design
Randomized controlled double-blind clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
Iron bioavailability, iron-calcium interaction

Interventions
The target sample will consist of pre-menopausal women aged 35 to 45 years old, from the South East Area of Santiago Metropolitan Area, Chile. A group of 14 subjects supplemented with 600 mg of carbonate calcium will be compared with a control group (n = 14) receiving placebo. Participants will be randomly assigned to both groups. Follow up had a duration of 43 days. It was established that assessment of iron bioavailability and tracers of iron absorption that will be used are 55Fe and 59Fe radioisotopes. Iron absorption will be determined by Eakins and Brown double radioisotope technique. Additionally iron status, anthropometry and dietary micronutrient intake will be measured. Sample size calculation was 9 childbearing age women per group based on a difference of iron absorption of 5% between intervention and control group, with a statistical significance of 95% and a power of 80%. Considering a possible loss of the number of subjects it was decided to recruit 14 women per group, which corresponds to a total of 28.

The intervention will last 58 days:
Day 1: Blood sample of 10ml to measure iron status. Heme iron intake labeled with 111 kBq of 55Fe, intake recorded and anthropometry
Day 2: Non heme iron intake labeled with 37 kBq 59Fe
Day 14: Blood sample of 20 ml to measure circulating radioactivity (cpm/ml)
Day 15: Beginning of supervised supplementation of carbonate calcium or placebo
Day 45: Intake of heme iron labeled with 111 kBq of 55Fe
Day 46: Intake of non heme iron intake labeled with 37 kBq of 59Fe

Day 57: Ending period of supervised supplementation of carbonate calcium or placebo
Day 58: Blood sample of 30 ml to measure circulating radioactivity (cpm/ml) and iron status

Bioavailability: For the administration of non heme radioisotope 50ml of an aqueous solution containing 3mg of iron as ferrous sulfate labeled with 37 kBq of 59FeCl3 will be used. For the administration of the non heme radioisotope 2 capsules with dried sheep red blood cells with 3mg of heme iron intrinsically labeled with 111 kBq of 55Fe will be used. Using 20 ml of blood, circulating radioactivity will be measured in accordance with Eakins and Brown double radioisotope technique (1966). 55Fe and 59Fe (NEN, Life Science Products, Inc., Boston, MA) will be quadrupled.
Iron status: 10 ml blood used to measure the following, hemoglobin (Hb), mean corpuscular volume (MCV) (CELL-DYN 1700, ABBOTT Diagnostics, Abbott Park, IL CEll Dyn), Zn protoporphyrin (Znpp) (Hematofluorometry ZP-M206D, AVIV Biomedical Inc., Lakewood, NJ).
Serum ferritin (SF) by an enzyme immuno assay of double sandwich (INACG)
Transferrin receptor (sTrF) and hepcidin by enzyme-linked immunosorbent assay (ELISA) (BioVendor, Laboratorní Medicína AS, Modrice, Czech Republic)
Serum iron, total iron binding capacity (TIBC) and transferrin saturation (Fisher and Price)
Anthropometry: Weight and height will be measured and compared with the patterns elaborated by World Health Organisation (WHO). Weight will be measured on a digital scale SECA ® with an accuracy of 0.1 kg, and length will be measured with a stadiometer of the same brand with an accuracy of 0.1 cm. 20. With these measurements body mass index (BMI) will be calculated as weight in kilograms divided by height (kg/m2). Weight and height will be used to determine blood volume using the table designated by Tulane
Dietary calcium and iron daily intake: at the beginning of the study, three 24 hour recalls will be administered each time, on different days in order to estimate calcium and iron daily intake. Micronutrients calculation will be performed according to the recommended daily allowance (RDA) for childbearing age women (Food and Nutrition Board)

Intervention Type
Supplement

Phase
Not Applicable

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

Primary outcome measure
1. Heme iron bioavailability
2. Non heme iron bioavailability

Secondary outcome measures
1. Iron status
1.1. Hemoglobin
1.2. Mean corpuscular volume
1.3. Zn protoporphyrin
1.4. Serum ferritin
1.5. Total iron binding capacity
1.6. Serum Iron
1.7. Hepcidin
1.8. Transferrin Receptor

1.9. Transferrin Saturation
1.10. Total body iron
2. Nutritional state by anthropometry
3. Dietary calcium and iron daily intake

Overall study start date
15/06/2011

Completion date
30/08/2011

Eligibility

Key inclusion criteria
1. Apparently healthy women
2. Thirty five to 45 years old
3. Not participating in other clinical studies
4. Contraceptive use

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Female

Target number of participants
28 women (14 will receive a calcium supplement and 14 a placebo)

Key exclusion criteria
1. Morbidity (excepting anemia defined as hemoglobin < 120 g/L)
2. Daily use of medicaments
3. Pregnancy and pregnant interest (including a pregnancy test before the start of the study)
4. Breastfeeding
5. Iron and/or calcium supplementation
6. Postmenopausal women
7. Participation in previous studies particularly involving the administration of radioactive labeled iron
8. Smoking

Date of first enrolment
15/06/2011

Date of final enrolment
30/08/2011

Locations

Countries of recruitment
Chile

Study participating centre
University of Chile
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Sponsor information

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University/education

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Funder(s)

Funder type
Research council

Funder Name
Fondo Nacional de Desarrollo Científico y Tecnológico (ref:1095038)

Alternative Name(s)

National Fund for Scientific and Technological Development, El Fondo Nacional de Desarrollo Científico y Tecnológico, FONDECYT

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Chile

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2014		Yes	No