ISRCTN48567380 https://doi.org/10.1186/ISRCTN48567380

Effect of calcium supplementation on iron status in children aged 6 to 8 years old supplemented with iron

Submission date
27/05/2011

Recruitment status
No longer recruiting

Registration date
29/06/2011

Overall study status
Completed

Last Edited
19/02/2016

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Iron is an essential mineral for humans, and is involved in many body processes such as the production of red blood cells. A lack of iron in the diet (iron deficiency) can lead to a reduction in the number of red blood cells (anemia). In Bolivia, iron deficiency is the most common nutritional disorder and the leading cause of anemia. Calcium is another mineral that is needed in humans, especially in growth periods. The aim of this study is to find out whether the supplementation of calcium and iron for 3 months has the same effect on iron status in children aged 6 to 8 years old compared with iron supplementation alone.

Who can participate?
Healthy children aged 6 to 8 years old

What does the study involve?
Participants are randomly allocated to receive a chewable pill containing either both calcium and iron or iron alone. Daily delivery of the supplements is carried out by a nutritionist or physician from the study team who monitors the risk of stomach upset. At the beginning and end of the study participants provide blood samples to allow us to determine their iron status.

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

Where is the study run from?
It was conducted in a school in the Municipality of Sucre, Department of Chuquisaca, Bolivia

When is the study starting and how long is it expected to run for?
August 2010 to November 2010

Who is funding the study?
Chilean Science Council

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

Type(s)
Scientific

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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
A randomized controlled trial investigating the effect of calcium supplementation on iron status in children aged 6 to 8 years old supplemented with iron in Sucre, Bolivia

Study objectives
Daily supplementation of 700mg of calcium plus 30mg of iron during 3 month has the same effect on iron status in children aged 6 to 8 years old compared with the supplementation of 30mg of iron.

This study was conducted in accordance with the Helsinki Declaration and the Nuremberg Code. Moreover, this study was approved by the health and educational authorities of the municipality of Sucre, Bolivia. Participation was voluntary, no remuneration was provided, and all subjects were free to withdraw at any stage of the study. Proceedings were done after parents read and signed the written informed consent and children assent.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee, Institute of Nutrition and Food Technology (INTA), University of Chile, 11/08/2010, ref: 17/2010

Study design

Randomized controlled double-blind clinical trial

Primary study design
Interventional

Study type(s)
Prevention

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

Interventions
1. This study was conducted in a school located in a low middle socio-economic sector in the Municipality of Sucre, Department of Chuquisaca, Bolivia
2. Age criteria (6 to 8 years) was based on the international consensus on the health benefits of early delivery of iron supplementation in vulnerable population groups
3. Subjects belonged the first two years of primary education. Moreover, the school allowed ensuring the daily delivery of the supplements
4. It was conformed two groups that were randomly assigned to receive 700mg of calcium as calcium carbonate and 30 mg of iron as ferrous sulfate
5. The second group received 30 mg of single iron as ferrous sulfate
6. In both cases supplementation consisted of one chewable pill with the same appearance
7. Daily delivery (11:00 am monday to friday) of the supplements was done personally by nutritionist or physician who were part of the study team
8. Follow up had a duration of 3 months
9. Minerals doses used and the time of follow up were based on the criteria proposed by FAO /WHO for population assistance in supplementation programs in school age
10. High amounts of both micronutrients were used due the high prevalence of anemia in Bolivia (National Health Survey 2009) and low intake of milk (FAO)
11. Sample size calculation was 88 school children per group based on an estimated prevalence of anemia of 15%, with an alpha level at 0.05 and a power of 80%
12. Considering a possible loss of 10%, the number of subjects in each group was 97, which correspond to a total of 194
13. At the beginning and end of the study were obtained ≈3 ml of venous blood in order to determine iron status. Moreover, it was measured anthropometry and feeding patterns
14. Iron status: In the Laboratory of Biochemistry, Faculty of Pharmacy and Biochemistry, University of San Francisco Xavier de Chuquisaca it was measured hemoglobin (Hb) (CELL-DYN 1700, ABBOTT Diagnostics, Abbott Park, IL CEll Dyn) and serum was separated and frozen at -22° C 15. In the Laboratory of Micronutrients at the Institute of Nutrition and Food Technology, University of Chile it was measured serum ferritin (SF) by an enzimo inmuno assay of double sandwich (INACG), transferrin receptor (sTrF) by ELISA (Human sTrF, BioVendor, Laboratorní Medicína AS, Modrice, Czech Republic) and C-Reactive Protein (CRP) (Array Protein System, Beckman Instruments)
16. Lower-normal limit for Hb used was 13.4 g/dL (equivalent to 12 g/dL adjusted by altitude), SF 15 µg/L and upper-normal limit for sTrF 8.3 µg (INAGG)
17. Anemia was defined with Hb below normal and IDA as hemoglobin below normal plus abnormal SF or sTrF; depleted iron stores were defined as normal Hb and SF below normal
18. Iron status was considered to be normal when all of these laboratory indexes were within the reference range. Additionally inflammatory processes were identified considering CRP >20mg/L.
19. Anthropometry: Weight and height were measured and compared with the patterns of child growth elaborated by CDC

20. Weight was measured on a digital scale Camry ® with 120 Kg of maximum capacity and an accuracy of 10 grams, and length was measured with a stadiometer
21. Measurement techniques were performed according to the guidelines for measuring anthropometric indicators of the FANTA project of the American Academy for Educational Development
22. Dietary pattern: two 24 hour recall were administered each time, on different days, before and after measuring food intake
23. Diet nutrients calculation was performed according to the RDA for school children (Food and Nutrition Board)

Intervention Type
Supplement

Primary outcome(s)
Iron status:
1. Hemoglobin
2. Serum ferritin
3. Transferrin Receptor

Key secondary outcome(s))
1. C-Reactive Protein
2. Nutritional state by anthropometry
3. Macronutrient and micronutrient daily intake
4. Total body iron

Completion date
12/11/2010

Eligibility

Key inclusion criteria
1. Apparently healthy
2. 6 to 8 years old
3. Not participating in other clinical studies
4. Public education

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
6 years

Upper age limit
8 years

Sex
All

Key exclusion criteria
1. Severe anemia: hemoglobin below 8.3 g/dL (equivalent to <7g/dL adjusted by altitude, Sucre is located at 2700 m.a.s.l, INACG)
2. C-Reactive Protein >20 mg/L
3. Illiterate parents
4. Children with micronutrient treatment in the past 6 months

Date of first enrolment
12/08/2010

Date of final enrolment
12/11/2010

Locations

Countries of recruitment
Bolivia

Chile

Study participating centre
El Libano 5540
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Sponsor information

Organisation
University of Chile (Chile)

ROR
https://ror.org/04teye511

Funder(s)

Funder type
Research council

Funder Name
Chilean Science Council (Fondo de Desarrollo Científico y Tecnológico) ref: FONDECYT Nº 1095038

Results and Publications

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes