ISRCTN11852796 https://doi.org/10.1186/ISRCTN11852796

Effect of combined iron, zinc, and calcium supplementation on iron, zinc, and calcium status in adolescents

Submission date
06/06/2014

Recruitment status
No longer recruiting

Registration date
20/06/2014

Overall study status
Completed

Last Edited
29/01/2019

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Iron (Fe), zinc (Zn), and calcium (Ca) are essential nutrients for humans. Not having enough of these nutrients in the diet can have negative effects on, for example, growth, psychomotor development (development of mental and physical skills), immunity and reproduction. Giving a combined supplement providing a particular amount of Fe, Zn and Ca should improve the nutritional status (the balance between intake of nutrients and the amounts needed by the body) of these nutrients. Adolescence is one of the times in our lives where nutrition is particularly important as its a period of rapid physical and mental growth and sexual maturity. The major aim of this study is to find out the effect of combined Fe, Zn and Ca supplementation on the nutritional status of these nutrients in adolescents.

Who can participate?
Adolescents between 16-18 years of age and classified as being at a certain stage of development (Tanner stage 5)

What does the study involve?
Patients are randomly allocated to one of four groups:
1. Calcium supplemented group (control group)
2. Calcium plus Fe supplemented group
3. Calcium plus Zn supplemented group
4. Calcium, Fe and Zn supplementation group
The study involves clinical, dietary, anthropometric (for example height and weight), and socio-demographic assessment before and after the supplementation period over 6 months.

What are the possible benefits and risks of participating?
The benefit is a full medical assessment to determine Fe and Ca nutritional status. Risks are not expected.

Where is the study run from?
The study runs in a low-income area of south-east Santiago and is managed by the Institute of Nutrition and Food Technologies (INTA), University of Chile, Santiago, Chile

When is the study starting and how long is it expected to run for?
July 2014 to October 2016

Who is funding the study?
National Fund for Scientific & Technological Development (FONDECYT), (Chile)

Who is the main contact?
Prof. Fernando Pizarro
fpizarro@inta.uchile.cl

Contact information

Type(s)
Scientific

Contact name
Prof Fernando Pizarro Aguirre

ORCID ID
http://orcid.org/0000-0001-6088-1119

Contact details
Institute of Nutrition and Food Technology (INTA)
University of Chile
El Líbano 5540
Macul
Santiago
Chile
13811
+56 (0)2 978 1522
fpizarro@inta.uchile.cl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Fondecyt Grant 1130090

Study information

Scientific Title

Effect of combined iron, zinc, and calcium supplementation on iron, zinc, and calcium status in adolescents: a randomized controlled trial

Study objectives
Combined iron, zinc, and calcium supplementation improves hematological indicators of iron, zinc, and calcium status in adolescents.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Ethics Committee of the Institute of Nutrition and Food Technology at the University of Chile, 27/06/2012, ref. resolution approval Nº 17

Study design
Randomized controlled double-blind clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Quality of life

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
Micronutrient deficiencies

Interventions
Current interventions as of 18/01/2017:
Patients will be randomly allocated to one of four groups:
1. Calcium supplemented group (control group)
2. Calcium plus Fe supplemented group
3. Calcium plus Zn supplemented group
4. Calcium, Fe and Zn supplemented group

The calcium (Ca) dose (500 mg) was defined based on 50% of the RDA for this age group. Iron and Zn doses will be established according with the current recommendation for these minerals. The supplementation period will last for 6 months.

Previous interventions:
Patients will be randomly allocated to one of four groups:
1. Calcium supplemented group (control group)

2. Calcium plus Fe supplemented group
3. Calcium plus Zn supplemented group
4. Calcium, Fe and Zn supplemented group

The calcium (Ca) dose (650 mg) was defined based on 50% of the RDA for this age group. Iron and Zn doses will be established according with the current recommendation for these minerals. The supplementation period will last for 12 months.

Intervention Type
Supplement

Primary outcome measure
1. Bone mineralization (as an outcome of Ca supplementation)
2. Iron nutrition status measured by:
2.1. Hemoglobin
2.2. Mean corpuscular volume
2.3. Zn protoporphyrin
2.4. Serum ferritin
2.5. Total iron binding capacity
2.6. Serum Iron
2.7. Hepcidin
2.8. Transferrin receptor
2.9. Transferrin saturation
2.10. Total body iron
3. Zinc nutrition status measured by circulating Zn levels

Secondary outcome measures
Not provided at time of registration

Overall study start date
06/06/2014

Completion date
30/10/2016

Eligibility

Key inclusion criteria
Current inclusion criteria as of 18/01/2017:
1. Male or female
2. 16 - 18 years old
3. In good health
4. Sexual maturity rating of Tanner stage 5

Previous inclusion criteria:
1. Male or female
2. 16 - 17 years old
3. In good health
4. Sexual maturity rating of Tanner stage 5

Participant type(s)

Patient

Age group
Child

Lower age limit
16 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
One hundred and sixty subjects (n=160), 50% female

Key exclusion criteria
1. Use of vitamin supplements containing iron, zinc, calcium, vitamin D during the last 6 months prior the beginning of the trial
2. Known intolerance/allergy to iron, zinc, and calcium supplements
3. Smoking and alcohol abuse or dependence
4. Morbidity (excepting anemia defined as hemoglobin < 120 g/L)
5. Participation in previous studies particularly involving the administration of micronutrient supplements
6. Pregnant or planning a pregnancy during the study period
7. Breastfeeding

Date of first enrolment
01/05/2015

Date of final enrolment
30/10/2016

Locations

Countries of recruitment
Chile

Study participating centre
Institute of Nutrition and Food Technology (INTA)
Santiago
Chile
13811

Sponsor information

Organisation
University of Chile (Chile)

Sponsor details
Institute of Nutrition and Food Technology (INTA)
El Líbano 5540
Macul
Santiago
Chile
13811
+56 (0)2 29781400
fpizarro@inta.uchile.cl

Sponsor type
University/education

Website
http://www.uchile.cl/

ROR
https://ror.org/04teye511

Funder(s)

Funder type
Government

Funder Name
Fondo Nacional de Desarrollo Científico y Tecnológico

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
31/12/2019

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?
Basic results		29/01/2019	29/01/2019	No	No