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Efficacy of different schemes of supplementation with micronutrient powder for the control of anemia and micronutrient deficiency in children

Submission date
02/05/2013

Recruitment status
No longer recruiting

Registration date
23/05/2013

Overall study status
Completed

Last Edited
23/05/2013

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 deficiency or anemia is the most common nutritional deficiency in the world. Infants and young children are at the highest risk of anemia because they have higher iron requirements. Iron syrup or drops are good in preventing or treating anemia but most children do not like them because of bad taste, therefore compliance is poor. There is an alternative method to treat anemia. Iron and micronutrients in powder (MNP) can be sprinkled and mixed with a portion of the baby food. They do not change the color or the taste of food. They are well accepted. Research shows that MNPs are good in reducing anemia. However, there is no agreement about how much should be used and for how long. This study aims to investigate the best usage of MNPs, with respect to the number of sachets, duration and form (daily or intermittent).

Who can participate?
Children 6-11 months old, living in the city of Cajamarca, Peru, born at term, with birth weight > 2.5 kg, without severe illness, severe anemia and severe malnutrition can participate.

What does the study involve?
Children are randomly allocated to one of four groups using a computer program. They will receive supplementation daily or weekly for 6 months or one year. All children will be followed for 12 months . There are blood tests at the beginning, during and after the study. All information collected are kept confidential.

What are the possible benefits and risks of participating?
Benefits include free examination by the pediatrician, supplements, lab analyses and health care. The information will help decide the best supplementation for small children. The dose of supplements is based on international recommendations of daily intake of nutrients. There is a low risk that blood drawn may cause a hematoma.

Where is the study run from?
The study is conducted in Cajamarca, Peru.

When is the study starting and how long is it expected to run for?
September 2011 to June 2013.

Who is funding the study?
Micronutrient Initiative, Canada
Lab analyses are supported by Sight and Life, Switzerland

Who is the main contact?
Dr. David Loza
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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
IIN-282

Study information

Scientific Title
Defining criteria to establish the optimum scheme of supplementation with micronutrient powder in children: unblinded randomized controlled trial

Study objectives

To investigate what is the optimal scheme of supplementation with MNP, regarding the number of sachets, duration and form of supplementation (daily or intermittent).

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Instituto de Investigacion Nutricional (IIN) Review Board (IRB) approved on the 14-03-2011: Reference 308-2011/CEI-IIN
2. Peruvian National Institute of Health authorized on the 10-06-2011. Reference 506-2011-DG-OGITT-OPE/INS

Study design
Unblinded randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Prevention

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
Anemia

Interventions
There are 4 groups of supplementation:
1. Children from 6 to 11 months of age, who consume the micronutrient powder supplement intermittently for 6 months (90 doses), will have a significant decrease in the prevalence of anemia and micronutrient deficiency (control group)
2. Children 6 to 11 months of age, who consume the micronutrient supplement powder intermittently for 12 months (180 doses), will have a greater decrease in the prevalence of anemia and micronutrient deficiency compared with the control group. (Group I)
3. Children 6 to 11 months of age, who consume the micronutrient supplement powder daily for 6 months (180 doses), will have a greater decrease in the prevalence of anemia and micronutrient deficiency compared with the control group. (Group II)
4. Children 6 to 11 months of age, who consume the micronutrient supplement in powder on a daily basis for 12 months (360 doses), will have a greater decrease in the prevalence of micronutrient deficiency anemia and the control group and groups I and II. (Group III).
The participation in a group is randomized, using a computer program

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Anemia prevalence. All children are followed for 12 months, at entry and every month children are examined by a pediatrician at the outpatient clinic, every 2 weeks a field worker visits the child´s home to record compliance and morbidity, at entry and at the end of supplementation a venous blood sample of 5 ml is taken to measure hemoglobin, and micronutrients. In 2 more times we will take a drop of blood from the finger to measure hemoglobin.

Secondary outcome measures
1. Growth (weight and length)
2. diarrhea prevalence
3. micronutrient status (ferritin, transferrin receptors)
4. vitamin A
5. vitamin B12
6. zinc and folate status
7. inflamatory markers (CRP, AGP)

Overall study start date
01/09/2011

Completion date
01/06/2013

Eligibility

Key inclusion criteria
1. Children between 6 months and 11 months and 29 days old
2. Residents in the city of Cajamarca and communities near the Health Center Baños del Inca
3. Born at term
4. Birth weight ≥ 2500 g
5. Healthy
6. Hemoglobin> 8 g/dL (corrected for altitude)
7. Weight / length> -2 SD
8. Parents agree and sign the informed consent form

Participant type(s)
Patient

Age group
Child

Lower age limit
6 Months

Upper age limit

11 Months

Sex
Both

Target number of participants
400

Key exclusion criteria
1. Children younger than 6 months, or more than 12 months
2. Non-residents in Cajamarca (intervention site)
3. Children with initial hemoglobin below 8 g/dL (corrected for altitude) will be evaluated by the doctor to discard additional pathology and will be treated according to Ministry of Health standards
4. Weight/length below - 2 DE
5. Chronic, congenital or severe diseases
6. Parents do not sign the informed consent form

Date of first enrolment
01/09/2011

Date of final enrolment
01/06/2013

Locations

Countries of recruitment
Peru

Study participating centre
Instituto de Investigación Nutricional
Lima
Peru
Lima 12

Sponsor information

Organisation
Micronutrient Initiative (Canada)

Sponsor details
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Sponsor type
Other

Website
http://www.micronutrient.org/

ROR
https://ror.org/05g1gph86

Funder(s)

Funder type
Other

Funder Name
MICRONUTRIENT INITIATIVE (Canada)

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