ISRCTN39244429 https://doi.org/10.1186/ISRCTN39244429

Nutritional supplement sprinkles with zinc and micronutrients

Submission date	Recruitment status	[ ] Prospectively registered
12/02/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
16/03/2010	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
15/03/2011	Nutritional, Metabolic, Endocrine	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
IIN-270

Study information

Scientific Title

Efficacy of the nutritional supplement sprinkles with zinc and micronutrients on anaemia and acute diarrhoea in Peruvian children

Acronym
SUNSZIM

Study objectives
1. Children 6 to 17 months of age that consume the nutritional supplement sprinkles with zinc and micronutrients for a 6 month period will have a lower prevalence of anaemia than will those children that consume the nutritional supplement sprinkles with iron alone.
2. Children 6 to 17 months of age that consume the nutritional supplement sprinkles with zinc and micronutrients for a 6 month period will have a lower incidence and prevalence of acute diarrhoea than will those children that consume the nutritional supplement sprinkles with iron alone.
3. Children 6 to 17 months of age that consume the nutritional supplement sprinkles with zinc and micronutrients for a 6 month period will have better growth than those children that consume the nutritional supplement sprinkles with iron alone.
4. The adherence of the nutritional supplement sprinkles with zinc and micronutrients and the nutritional supplement sprinkles with iron alone will be similar, in both cases greater than 75% of the offered doses.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Instituto de Investigacion Nutricional (IIN) Institutional Review Board (IRB) approved on the 26th of June 2009 (ref: 284-2009/CEI-IIN)
2. Mount Sinai Hospital IRB approved on the 22nd of October 2009
3. Peruvian NIH authorisation received on the 18th of September 2009

Study design
Interventional single centre phase III double blind randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
Anaemia and diarrhoea

Interventions

Research product:
Micronutrient supplement as sprinkles, packaged into individual sachets, each sachet intended for once daily use to be mixed with food. The iron portion of the powder is lipid encapsulated to prevent changing the taste, texture, or colour of the food. The composition used in this study is outlined in the table below.

Micronutrient Amount
Iron as fumarate 12.5mg
Zinc as gluconate 10 mg
Folic Acid 160mcg
Vitamin A 300mcg RE
Vitamin C 30mg

Control Product:
The control group is also a powdered sprinkles form having the following composition per sachet.
Micronutrients Quantity
Iron as fumarate 12.5mg
Route of administration (both groups): Oral
Presentation Form: Powder
Duration of supplementation per subject: 6 months.

Intervention Type

Other

Phase

Phase III

Primary outcome measure

1. Anemia:
Haemoglobin (Hb) is measured by HemoCue® at baseline and 6 months later (end of the study participation). Prevalence of anaemia is the percentage of children with Hb below 11 g/dl (WHO definition). We will also compare mean Hb values at baseline and end of the study.
2. Diarrhoea:
Morbidity is recorded by home surveillance once a week and we register the daily morbidity, prevalence of diarrhoea is registered as the days with morbidity over the number of observation days x 100, incidence as number of episodes of diarrhoea per 100 days of observations.

Secondary outcome measures

1. Incidence of severe diarrhoea:
Severe diarrhoea is defined as ≥ 6 liquid or loose stools in the last 24 hr, number of episodes of severe diarrhoea per 100 days of observations.
2. Duration of diarrhoea:
Number of days with diarrhoea (≥ 3 liquid or loose stools in the last 24 hr).
3. Adherence to supplementation:
Number of sachets consumed during the study per over the number of sachets given x 100.
4. Changes in weight and length:
Anthropometric measures weight and length will be taken on infants at baseline and monthly through 6 months of intervention, and Z scores determined for weight-for-age (WAZ), length-for-

age (LAZ), and weight-for-length (WLZ) compared to WHO references.
5. Serum zinc:
Measured at entry and 6 months post supplementation.

Overall study start date
07/01/2010

Completion date
31/01/2011

Eligibility

Key inclusion criteria
1. Aged between 6 months and 17 months, 29 days of age
2. Residents of Villa El Salvador, Lima, Peru
3. Born at term
4. Birth weight equal or higher than 2500g
5. Healthy
6. Parents agree to sign the informed consent form

Participant type(s)
Patient

Age group
Child

Lower age limit
6 Months

Upper age limit
17 Months

Sex
Both

Target number of participants
902

Key exclusion criteria
1. Age less than 6 months, or equal to/greater than 18 months
2. Not residents in the area of intervention
3. Children with an initial haemoglobin equal to or less than 8g/dL will be evaluated by a doctor to rule out some additional pathology and will receive treatment according to Peruvian Ministry of Health (Ministerio de Salud [MINSA]) norms
4. Weight/Length less than -2 Standard Deviations (SD)
5. Any chronic, congenital, or severe illnesses
6. Children that regularly consume other micronutrient supplements

Date of first enrolment
07/01/2010

Date of final enrolment
31/01/2011

Locations

Countries of recruitment
Peru

Study participating centre
Av. La Molina 1885
Lima
Peru
Lima 12

Sponsor information

Organisation
Instituto de Investigación Nutricional (IIN) (Peru)

Sponsor details
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Sponsor type
Research organisation

ROR
https://ror.org/05by4rq81

Funder(s)

Funder type
Charity

Funder Name
United Nations Children's Fund (UNICEF) (USA)

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