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# 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

**Protocol serial number**
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

## Study type(s)
Prevention

## 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(s)
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.

### Key secondary outcome(s))
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.

### 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

### Healthy volunteers allowed
No

### Age group
Child

### Lower age limit
6 months

### Upper age limit
17 months

### Sex
All

### 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)

**ROR**
https://ror.org/05by4rq81

# Funder(s)

**Funder type**
Charity

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

# Results and Publications

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**
Not provided at time of registration