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Iron and zinc absorption in anaemic infants

Submission date	Recruitment status	[ ] Prospectively registered
18/11/2005	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
18/11/2005	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
18/04/2008	Haematological Disorders	[ ] 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
MCT-44156

Study information

Scientific Title

Study objectives
1. To measure the absorption of two different doses of iron from Sprinkles when added to a cereal-based complementary food provided to anaemic and non-anaemic infants (Study I)
2. To determine whether there is a difference in the absorption of zinc at two different zinc doses and a constant iron dose (Study II)
3. To examine whether zinc and ascorbic acid have an effect on the absorption of iron from Sprinkles (Study III)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Hospital for Sick Children (HSC) Research Ethics Board, 20 Jun 2001

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

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

Interventions
Ingestion (with a cereal-based weaning food) of micronutrient Sprinkles containing intrinsically labeled iron and/or zinc (stable isotopes) with added vitamin A and ascorbic acid.
Group 1: 30 mg elemental iron, 5 mg zinc and 50 mg
ascorbic acid
Group 2: 30 mg elemental iron, 10 mg zinc and 50 mg ascorbic acid
Group 3 with 30 mg elemental iron, 5 mg zinc and no ascorbic acid
All groups also contained 300 µg RE of retinol acetate vitamin A.

Trial details received: 12 Sept 2005

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Iron and zinc

Primary outcome measure
To determine percent absorption of iron and zinc from micronutrient Sprinkles

Secondary outcome measures
To examine whether zinc and ascorbic acid have an effect on the absorption of iron from sprinkles.

Overall study start date
01/02/2002

Completion date
30/09/2002

Eligibility

Key inclusion criteria
1. 6-24 months of age, either sex
2. Ingesting weaning foods in addition to breast milk
3. Free from major illness (including malaria)
4. Afebrile
5. Haemoglobin ≥70 g/l
6. Parental consent obtained

Participant type(s)
Patient

Age group
Child

Lower age limit
6 Months

Upper age limit
24 Months

Sex
Both

Target number of participants
88

Key exclusion criteria
1. Children with symptomatic malaria
2. Children with severe anaemia (Haemoglobin <70 g/l)

Date of first enrolment
01/02/2002

Date of final enrolment
30/09/2002

Locations

Countries of recruitment
Canada

India

Study participating centre
The Hospital for Sick Children
Toronto
Canada
M5G 1X8

Sponsor information

Organisation
Hospital for Sick Children (Canada)

Sponsor details
555 University Avenue
Toronto
Canada
M5G 1X8

Sponsor type
Not defined

ROR
https://ror.org/057q4rt57

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-44156)

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