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

Contact name

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Contact details

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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

M5G 1X8

India

Study participating centre
The Hospital for Sick Children
Toronto
Canada

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 planNot provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot provided at time of registration