

Iron and zinc absorption in anaemic infants

Submission date 18/11/2005	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 18/11/2005	Overall study status Completed	☐ Protocol
Last Edited 18/04/2008	Condition category Haematological Disorders	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☐ 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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Additional identifiers

Protocol serial number

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

Study type(s)

Not Specified

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(s)

To determine percent absorption of iron and zinc from micronutrient Sprinkles

Key secondary outcome(s))

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

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

6 months

Upper age limit

24 months

Sex

All

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)

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration