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'Sprinkles': a new approach to reduce anaemia among children in India

Submission date	Recruitment status	[_] Prospectively registered
12/09/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/12/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
25/02/2009	Haematological Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00213161

Protocol serial number
GLH-63082

Study information

Scientific Title

Establishing an iron supplementation strategy to reduce the prevalence of iron deficiency anaemia among infants and young children in India

Study objectives
The response to a 14.25 mg iron dose from drops will be greater than the response to a similar iron dose from Sprinkles, and will be equivalent to either a 20 or 30 mg iron dose from Sprinkles (either as encapsulated ferrous fumarate or micronized ferric pyrophosphate).

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Research Ethics Board of the Hospital for Sick Children, Toronto, Ontario (Canada) approved on the 16th February 2004 (ref: 0019970046)
2. Indian Council of Medical Research, New Delhi (India) approved on the 6th May 2004 (ref: IND /FRC/442/2004-IHD)

Study design
Single centre, interventional, 5 arms, randomised cluster trial with study participant, study investigator, caregiver, outcome assessor, and data analyst blinded

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Three different doses of Sprinkles: 12.5 mg, 20 mg, and 30 mg of elemental iron, and two forms of iron (encapsulated ferrous fumarate and micronized ferric pyrophosphate) compared to the standard and recommended dose of iron drops in India (Fersoft drops -14.25 mg Fe), daily for 2 months.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Sprinkles (encapsulated ferrous fumarate and micronized ferric pyrophosphate), Fersoft drops

Primary outcome(s)
Haemoglobin, measured at 4 weeks, 8 weeks, 8 months after first dosing.

Key secondary outcome(s))

1. Serum ferritin, measured at 8 weeks
2. Side effects, measured every 2 weeks

Completion date
01/12/2005

Eligibility

Key inclusion criteria
1. 6 - 18 months of age, either sex
2. Anaemic (haemoglobin [Hb] 70 - 100 g/L)
3. Ingesting weaning food in addition to breast milk
4. Free from major illness (including symptomatic for malaria) and afebrile
5. Living within study area for the following two months
6. Parental consent obtained
7. Only one child per household in the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
6 months

Upper age limit
18 months

Sex
All

Key exclusion criteria
1. Hb less than 70 or greater than or equal to 100 g/L
2. Not receiving any complementary foods
3. Receiving an iron supplement within two weeks of the date of enrolment
4. Chronic illness
5. Severely malnourished: weight for age z-score less than -3.0
6. Another child in the household is a subject in this study

Date of first enrolment
01/08/2004

Date of final enrolment
01/12/2005

Locations

Countries of recruitment
Canada

India

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

Sponsor information

Organisation
Research Institute 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: GLH-63082)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Results article	results	01/02/2007	Yes	No