

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

Submission date
12/09/2005

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
21/12/2007

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
25/02/2009

Condition category
Haematological Disorders

☐ Individual participant data

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

NCT00213161

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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 measure

Haemoglobin, measured at 4 weeks, 8 weeks, 8 months after first dosing.

Secondary outcome measures

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

Overall study start date

01/08/2004

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

Age group

Child

Lower age limit

6 Months

Upper age limit

18 Months

Sex

Both

Target number of participants

425

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)

Sponsor details

555 University Avenue

Toronto

Canada

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stanley.zlotkin@sickkids.ca

Sponsor type

Research organisation

Website

<http://www.sickkids.ca/>

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

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2007		Yes	No