

Intervention study to reduce the level of anaemia among infants

Submission date	Recruitment status	<input type="checkbox"/> Prospectively registered
24/01/2011	No longer recruiting	<input type="checkbox"/> Protocol
Registration date	Overall study status	<input type="checkbox"/> Statistical analysis plan
19/05/2011	Completed	<input type="checkbox"/> Results
Last Edited	Condition category	<input type="checkbox"/> Individual participant data
19/05/2011	Haematological Disorders	<input type="checkbox"/> 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

N/A

Study information

Scientific Title

Quasi study using two types of iron: a non-randomised controlled intervention trial

Study objectives

The introduction of ferrous sulphate at 6 months is suboptimal to the introduction of polymaltose complex iron preparation at 4 months in reducing the level of anaemia at 12 months. Iron preparation needs to be introduced earlier, at 4 months not 6 months and polymaltose complex is more palatable and has less gastrointestinal effects compared to ferrous sulphate.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Local Ethics Committee approved on the 1st September 2008

Study design

Quasi experimental non-randomised controlled intervention trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Anaemia

Interventions

1. Ferrous sulphate (control group)

1.1. Dose is 2 mg/kg/day, starting at 6 months of age, giving 3 bottles to last for 3 months for when the next follow up visit is due

1.2. Total duration is 6 months

1.3. Haemoglobin measured at 12 months

2. Iron polymaltose complex (intervention group)

2.1. Dose is 2 mg/kg/day, starting at 4 months of age, giving 2 bottles, 3 bottles and another 3 bottles to coincide with visits at 4, 6, 9 months

2.2. Total duration is 8 months

2.3. Haemoglobin measured at 12 months.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Haemoglobin level at 12 months

Key secondary outcome(s)

1. Feeding practices
2. Side effects of iron preparation
3. Compliance information

4. Family history of thalassaemia

4. Measures obtained via interview after the mother has performed the blood test for her child and before the results of the blood test, i.e., before her next visit to the clinic

Completion date

31/08/2010

Eligibility

Key inclusion criteria

All infants attending the 4 and 6 months immunization

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

4 months

Upper age limit

6 months

Sex

All

Key exclusion criteria

1. Already taking iron
2. Pre-term or of low birth weight (only excluded if infants were already taking iron)
3. Mother refused consent
4. Does not have a file at the clinic

Date of first enrolment

01/11/2009

Date of final enrolment

31/08/2010

Locations

Countries of recruitment

Palestine, State of

Study participating centre

Birzeit University

Ramallah

Palestine, State of

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Sponsor information

Organisation

Institute of Community and Public Health (Palestinian Territory)

Funder(s)

Funder type

Research organisation

Funder Name

Swedish International Development Cooperation Agency (SIDA) (Sweden)

Funder Name

Palestine Solidarity Association (PGS) (Sweden)

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?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes