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Intervention study to reduce the level of anaemia among infants

Submission date	Recruitment status	[ ] Prospectively registered
24/01/2011	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
19/05/2011	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
19/05/2011	Haematological Disorders	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Non randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet (Arabic only)

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 measure
Haemoglobin level at 12 months

Secondary outcome measures
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

Overall study start date
01/11/2009

Completion date
31/08/2010

Eligibility

Key inclusion criteria
All infants attending the 4 and 6 months immunization

Participant type(s)
Patient

Age group
Child

Lower age limit
4 Months

Upper age limit
6 Months

Sex
Both

Target number of participants
320 in each group

Key exclusion criteria
1. Already taking iron
2. Pre-term or of low bith 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)

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Sponsor type
Research organisation

Website
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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

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